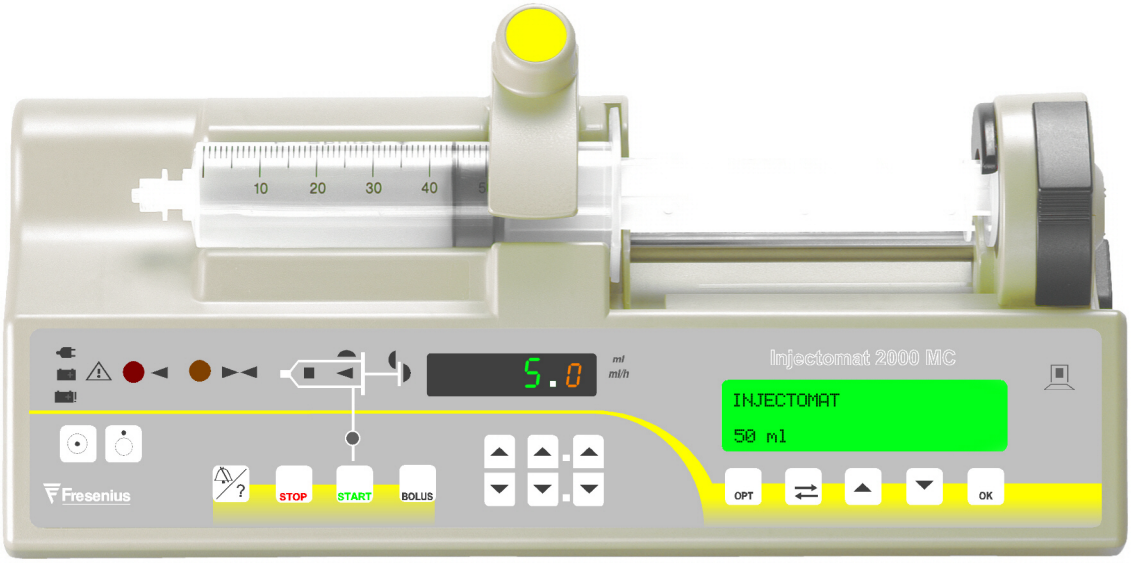
TECHNICAL MANUAL

Injectomat 2000 MC



CE 0459

Fresenius Vial
Infusion Technology

TABLE OF CHANGES

The information given in this document only concern devices of Injectomat 2000 MC / Pilot Delta

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Date	Revision no.	Pages concerned	Changes
01/08/00	A0	all	creation
02/07/02	B0	55 & 61	• Reference Injectomat 2000 MC / Pilot Delta RS232 HE13 power supply board, • Equivalence table

Fresenius Vial
Infusion Technology

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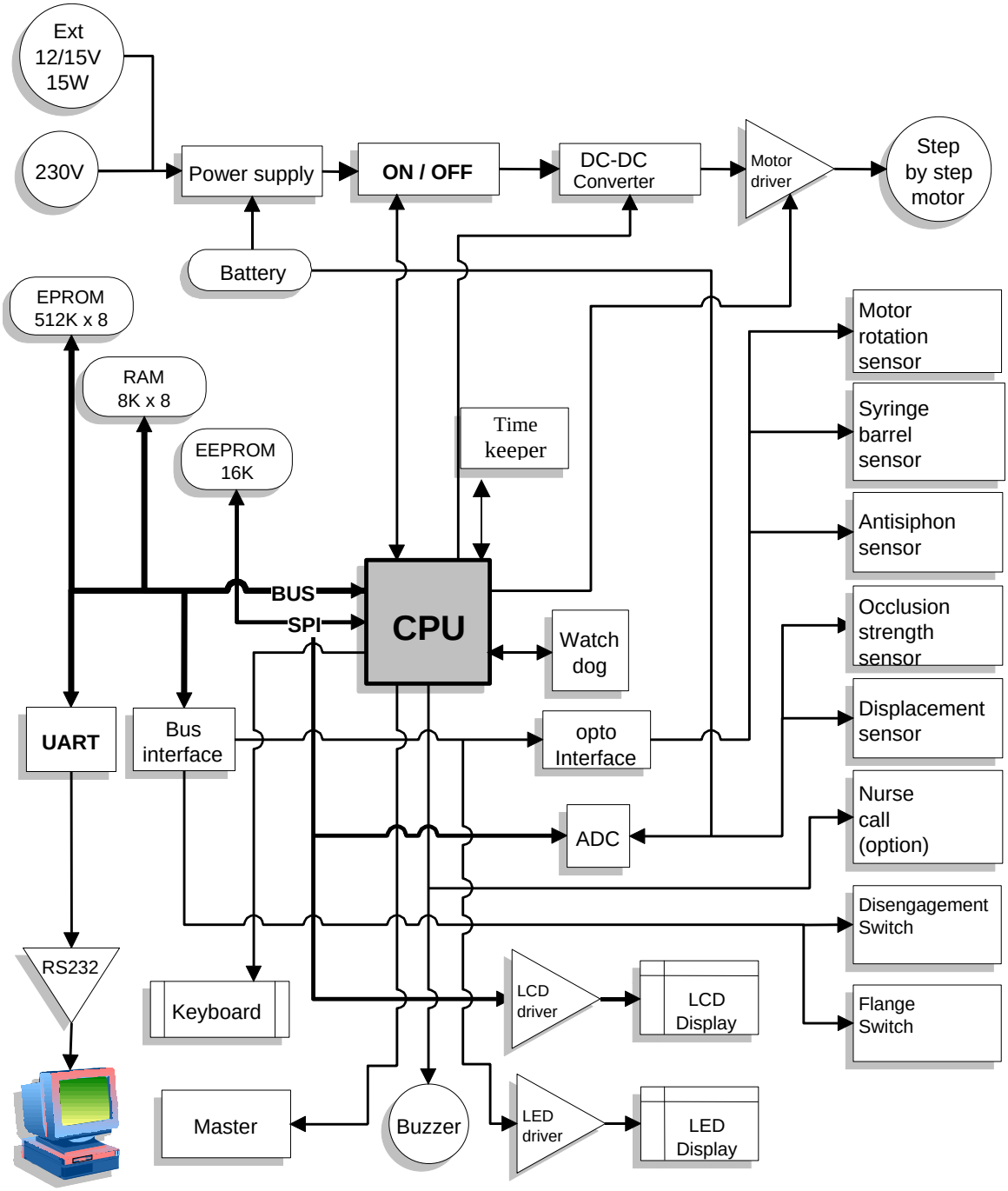
1 OVERVIEW

1.1. Block diagram



1.2. Precautions before use

Please consult the user guide

1.3. Overall product specifications

1.3.1. Biological specifications

Infusion liquid only comes into contact with the syringe and associated disposable.

1.3.2. Mechanical specifications

Device operation is based on a "lead screew/nut" principle. The mechanism pushes the piston of a syringe, of a given diameter, in a linear manner.

1.3.3. Dimensions

- H x L x D 120 x 330 x 155 mm.
- CarrWeight 2.2 kg approximately.

1.3.4. Electrical specifications

- Power supply 230V - 50-60 Hz.(Check on the pump the identification label).
- Maximum consumption 23 VA.
- Fuse F2 100 mAT 250V IEC 127
- Battery 6V - 1.2Ah./1.3 Ah
- External power supply 12 - 15 DC - 15W

1.3.5. Electronic specifications

The Injectomat 2000 MC / Pilot Delta syringe pump is fitted with 3 circuit boards whose features vary in line with product specifications and options.

- Motor power supply and control board.
- CPU board.
- Keyboard display board.

1.3.6. Injectomat 2000 MC / Pilot Delta Operator's guide

Operator's Guide can be obtained from our After Sales Service (see chapter 10.Useful addresses).

2 ELECTRONIC BOARD

2.1. MOTOR POWER SUPPLY AND CONTROL BOARD

2.1.1. Functional description

In order to simplify wiring the motor power supply control board concentrates 6 functional modules, which may be described separately:

- power supply module,
- motor control module,
- analog output module,
- disengage and anti-siphon opto switch module,
- microswitch input module,
- optional nurse call and RS232 interface module.

2.1.1.1. Power supply module

The power supply module consists of a cut-out power unit. It supplies all electronic components and charges a 1,1 -1,2 or 1,3 Ah backup battery from a mains voltage input or a 12/15 volt DC power source. It generates the + 5V and Vbat voltage required by the electronic components. Finally it comprises an ON/OFF switch controlling the various power supplies.

2.1.1.1.1. Mains power supply

The mains power supply generates a DC voltage ranging from 10 and 16 volts for a maximum current of 1,2 A.

J1 mains input connector:	1 phase
	2 neutral
Transformer:	TR1(see Electrical chart), 15VA output voltage: 9 Vac
Fuse protection:	F2 Principal characteristics chap1.1
Primary filtering	4.7 nf 4000 V HR capacitor, type DS1510 VDE
Secondary filtering	C10 Chemical Capacitor

Output voltage measured on TP3 for mains voltage: 230V measured (± 10%)

	Min	Max	Unit
power off:	14	16	V dc
7 ohm charged on J4:	10	16	V dc
primary current charged:		80	mA ac
Maximum voltage	16 volts limited by the diode D 41		
Minimum voltage	10 volts limited by the mains voltage - 10% and U1(MAX 652)		
	voltage higher than 10 volts.		

2.1.1.1.2. External 12-15V AC/DC power supply

The DC power supply input is designed to provide the syringe pump with a constant, external power source, such as a 12V battery.

Maximum input voltage	± 15 volts protection against polarity inversion by the PR2 WO4 diode bridge.
Minimum input voltage	± 11 volts 1.2 A limited by input voltage MAX 625 and loss, diode bridge on the PR2.
Limitation	± 16 volts maximum for through D 41.

2.1.1.1.3. Cut-out charger/controller

The controller is powered either from the mains or from an external DC power source. It generates a maximum voltage of 6.9V VBC, as required to charge the 1.1/1.2 Ah gelified lead battery, connected to J4, and power the electronic components.

J4 Connector:	1	battery +
	2	battery -

VBC power comes directly from the battery if neither the mains nor the external power source are connected. Otherwise power, from an external source, supplies the electronic components and charges the battery via diode D8 and the delayed protection fuse, F1, 1.6A.

Maximum fuse resistance 0.5 Ohms

Controller operation is indicated by two signals responsible for reporting operation using an external power source either mains power or the external *DC* power unit.

LDSECT 10 mA drives a diode which checks that the SECT diode is on, using a TTL signal, with + 5V pull up collector open, mains presence active at 0.

Cut-out controller: U1(MAX625) output voltage 7.05V 1.3 A min

Output voltage measured on J4.1

for 230 V mains:

	Min.	Max.	Unit
Power OFF 3 mA charge on J4. :	6.7V	7V	V DC
8 ohm charge on J4:	6.5V	7V	V DC

On J4 the voltage must never exceed 7V, the maximum voltage of the charged battery. The 6.5 minimum voltage is higher than the battery pre-alarm threshold.

2.1.1.1.4. ON/OFF control

The VBAT and + 5V control system is implemented using the following circuits: U2 4011, U4 4528 and an G6AK 234P flip-flop relay.
This system is powered, at all times, by the VBC voltage.

2.1.1.1.4.1 System:

3 inputs:		
TON	ON key	dry contact/GND
TOFF	OFF key	dry contact/GND
CDALIM	active TTL signal with voltage cut-out	

2 ouputs:	
VBAT	Battery power/mains power.
OFF	TTL signal collector, + 5V PULL-UP open, OFF key pressed down, active at 0

2.1.1.1.4.2 Operation:

Press TON briefly to turn power on.

Press TOFF continuously (5s<t<7s) to turn power off during a technical Failure.

Press OFF 3 seconds to power OFF via CDALIM micro signal.

The device can set ON or OFF via an external. Master module using the CD ON or CD OFF signal.

2.1.1.1.5. VBAT and + 5V power supply

VBAT voltage corresponds to mains voltage taken directly from the power unit/charger. Voltage is not controlled. It powers the display system and the motor, both of which are heavy duty energy consumers.

This voltage is available on TP1 and J2

	Min	Max
VBAT	6,5V	7V

The + 5V ± 5% is generated, using VBAT voltage, by the NS 2931 V3 controller low drop-out 0.6V for a 100 mA output current.

It is thus possible to make the best possible use of the battery. This voltage is available on TP2.

The 5V rise time must be greater than 100 ms to allow for the RESET function on the CPU board.

2.1.1.2. Motor control module

The control module of step by step motor is equipped with a gear reduction of 89.286. which makes the double threaded screw 2 mm turn.

- One motor step is equivalent to 0.8233 µm of linear displacement of the driving bloc.

- One motor turn is equivalent to 22.4 µm of linear displacement of the driving bloc.

2.1.1.2.1. Motor control

Injectomat 2000 MC / Pilot Delta motor control is implemented by a stepper motor driver, dual pole control module for a motor - UBB 5N model - (11.5 Ohm coil) built using an ST L293E IC7 motor control circuit.

It features two functional modules:

The motor control electronic parts, built around the L293E U13 circuit, optimises consumption and optimal motor torque according to the pump flow rate.

2.1.1.2.1.1 Input signals

These signals are generated by the CPU board microprocessor and available on J02.

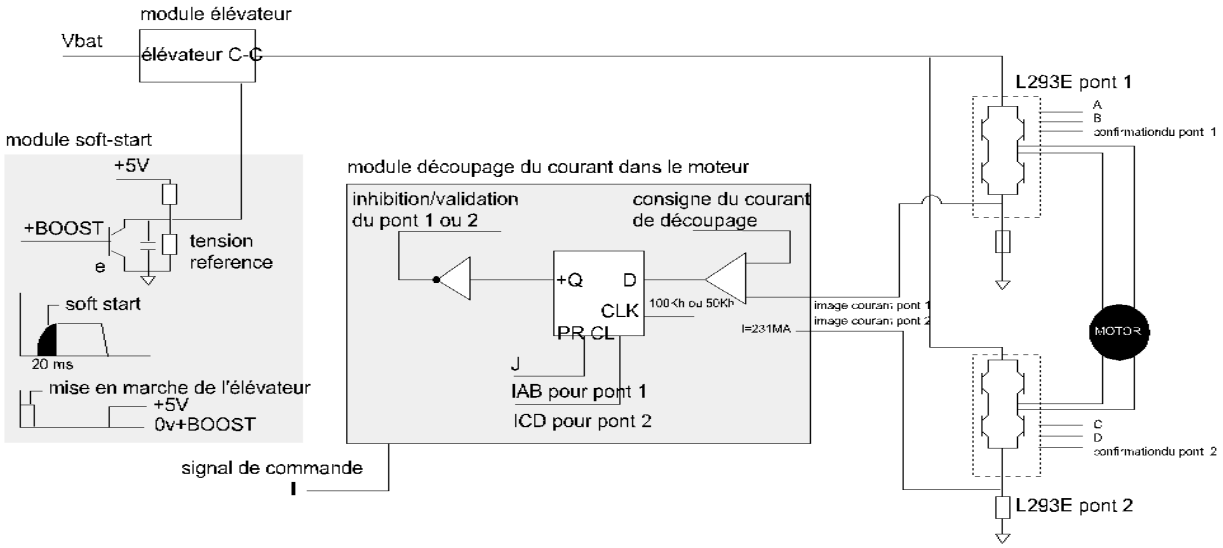
They drive the U15 ULN2803 circuit.

2.1.1.2.1.2 Output signals

These signals are connected to the motor coils via J5 connector.

Phase A	A Motor phase control	J2.5
Phase B	B Motor phase control	J2.6
Phase C	C Motor phase control	J2.7
Phase D	D Motor phase control	J2.8
I	Motor current reduction control	J2.9
B00ST	Booster activation and regulation current	J2.10

2.1.1.2.1.3 Booster module



BOOST = 0 The motor is powered via VBAT voltage.

BOOST = 1 Booster function activated, the motor is powered at 12 Volts.

L2 reactor, D18 diode, C15 capacitor and T8 transistor assembly allows a voltage of 12 V +/- 2 volts to be obtained from VBAT.

This voltage is available on TP5.

The uncoupling frequency, 100 kHz, is generated by U9 oscillator, the booster is activated when the boost line is at 1.

2.1.1.2.1.4 Soft-start module

The soft-start module, which is designed around the T9 transistor and C21 capacitor allows the pick up current of the uncoupling elevator to be limited when BOOST goes to 1.

2.1.1.2.1.5 Current regulation module

BOOST = 1 and I = 1 regulation motor current module is activated.

The regulated current in the motor is 240 mA +/- 10% per motor phase.

The signals amplitude and current image are available in TP6 and TP7.

The current image of each coil is compared to a fixed level, which is implemented from the Divider bridge using R31, R41/R37 and R42.

The control is achieved through the U11 toggle, via a divider bridge by inhibition or confirmation of the L293E control H bridge driving the CE1 and CE2 inputs.

The calibrating frequency of 25 kHz is supplied by the U10 toggle.

2.1.1.2.1.6 Reduction current module

When the Boost signal sets at 0, the I line is used as current reducer.

I = 1	The H divider bridge is controlled by the A, B,C and D lines.
I = 0	The H divider bridge is inhibited, the coils are not forwarded.

According to its rotation frequency (step/second), the motor is driven in one of the 3 control modes.

Mode	Frequency motor (step/second)	Control description
Phase 1	from 0 to 32.3	Current reduction one ON supply
Phase 2	from 32.3 to 90	No current reduction and regulation, one ON supply
Phase 3	from 90 to 850	Current reduction, booster ON two supply

2.1.1.3. Analog output module

The analog output module is built around a 10 bit, 5 channel analog/digital converter (MC 145053 U17) with an SPI bus.
The following SPI CLK, SI, SO, CSADC bus signals are available on connector J2:
In addition the component generates an end of conversion signal (EOC).
The CDANA signal, which is active when set to 1, controls the transistor T14 IRFD 9120 which digitally drives VREF. This voltage supplies the sensors and serves as a reference value for the ADC convertor.
All the test points are concentrated on connector J9.
Measurement of VREF on J9.7

VREF	Pulsated signal of 5Volt ± 0.25V.

Convertor input:

AN0	VBAT battery voltage measurement.
AN1	not in use
AN2	internal occlusion gauge bridge
AN3	NU
AN4	Absolute potentiometric position sensor

2.1.1.3.1. Battery voltage measurement

VBAT voltage is measured using a peak detection circuit comprising D19, R59, R60 and C23 in order to overcome the lower voltage created by the motor's pulsing demand for current.
The voltage is available on J9.3.

For VBAT = 6.5V, V(J9.3)= 4V ± 10% motor running at 150 ml/h

2.1.1.3.2. Gauge bridge interfaces

The only Injectomat 2000 MC / Pilot Delta includes a force sensor fixed on the pusher.

2.1.1.3.2.1 Force sensor characteristics

Sensor technical	Complete bridge with 4 gauges
Impedance	350 Ohms ± 15% or 1 KOhms ± 15%
Measurement range	0 to 150 N
Surcharge	250 N
Zero	< ± 10mV
Sensibility	8.5 to 12 mV at 150 N
zero derivation	85 µV /year

2.1.1.3.2.2 Operation

The force sensor generates a differential voltage proportional to the force sensor applied on the driving bloc. This force is amplified by a gain of 200 +/- 20% via an amplifier built around U18 TLC 251. The potentiometer P1 allows the offset to be compensated and for any other offset to be reset from the beginning. The sensor measurement chain transfer function can be defined by calibrating the sensor with two known forces.

AN3 J9.4 Pulsated amplitude signal sets at 0.6 V +/- 0.05 V for no force applied on the driving bloc

2.1.1.3.2.3 Force sensor connector

J8.1	VREF	Gauge bridge power supply (+)
J8.2	S(-)	Out put Gauge bridge (-)
J8.3	S(+)	Out put Gauge bridge (+)
J8.4	GND	Gauge bridge power supply (-)

2.1.1.3.3. Driving bloc position sensor

The absolute position of the driving bloc is obtained by a potentiometric sensor driven by a movement of the driving bloc.

The transfer function of the sensor can be characterised by calibration in two known positions.

The sensor is powered by a pulsated voltage. The output is filtered by R62 and C22 linked directly to the input AN4 (J2)

Potentiometer connector:

J3.1	VREF	
J3.2	Center point	J9.2
J3.3	GND	

2.1.1.4. Opto switch module

The opto switch module comprise 2 optical switches:

- A motor rotation detection switch
- A syringe position head detector switch

2.1.1.4.1. Motor rotation opto

The opto switch is mounted on a disk which is pierced with a hole and assembled on the motor.

It is used to check motor rotation, the opto diode is controlled in pulse mode to save energy.

The optical switch is connected on J5.

Control	T11 transistor	Current limitation (R51) at 8mA
Output	T10 transistor	TTL level
J2.14	Control signal CDOPT1	activate at 1
J2.11	Output signal SOPT1	activate at 1
J5.7	Diode anode	
J5.8	Diode cathode	
J5.10	Transistor transmitter	
J5.9	Transistor collector	
TdON	max 100 µsec	
TdOFF	max 200 µsec	

An anti-rebound device made of U20 flip-flop, reshapes the SOPT1 signal.

The CDOPT1 and SOPT1 are emitted by the CPU board, and available on J2 connector

2.1.1.4.2. Anti-siphon opto switch

The opto switch is mounted on the plunger holder, it is used to check the presence or not of the syringe head.

It is connected on J8 connector.

Control	T12 Transistor	Current limitation (R52) 8mA	
Output	T13 Transistor	TTL level	
Control signal	CDOPT2	activate at 1	J2.15
Output signal	SOPT2	activate at 1	J2.12
Anode diode			J8.6
Cathode diode			J8.5
Transistor transmitter		common ground	J8.10
Transistor collector			J8.7
SOPT2	0V	Anti - siphon present	
SOPT2	5V	Anti - siphon missing	

J8 is the ribbon cable linking the occlusion, disengagement and position sensors located on the syringe pump driver.
The CDOPT2 and SOPT2 signals are emitted by the CPU board and available on J2 connector.
The opto diode is powered by pulsated voltage in order to save energy.

2.1.1.5. Micro switch module

2.1.1.5.1. Disengagement micro - switch

The microswitch is mounted on the driving bloc ribbon cable. The centre point of the microswitch is connected to the ground.

The signals are available on J2 connector.

J8.8	DEB/ON	NU
J8.9	DEB/OFF	OV engaged / 5V disengaged
J8.10	GRD	

2.1.1.5.2. Nurse call option

This is implemented by a monostable inverter relay RL2, whose two contacts and common point are available on J6 connector, the relay is driven by the BUZ signal which also drives the buzzer on the display board.

J6.6	common point
J6.7	contact normally open cut out power 24V/ 1A
J6.8	contact normally shut

2.1.1.5.3. RS 232 option

The RS232 option interface RXD1 and TXD1 signals, in compliance with the V24 standard, signals come from the UART 2691 serial link external controller on the CPU board. It is implemented using a U19 LT 1180 CS circuit, associated with +/- 12V voltage generator, C31, C32, C33, C34 capacitors. This circuit is operational only if the pins 2 and 5 of J6 are short-circuited.

J6.1	output transmits data TX1
J6.2	+5V (DSR)
J6.3	input receives data RX1
J6.4	GND
J6.5	confirmation (DTR)
J6.17	CTS
J6.18	RTS

2.1.1.5.4. Configuration link and Master plug

The syringe pump Injectomat 2000 MC / Pilot Delta may be fitted to master module connected to the SUB 15 points plug located on the pump rear panel.

The module master communication link is done by the RX2 and TX2 signals.

J6.13	+VBAT	Master power
J6.14	RX2	Receive data
J6.15	TX2	Transmit data
J6.16	GND	Master ground
J6.9	CD-ON	Syringe pump ON via master
J6.10	CD-OFF	Syringe pump OFF via master
J6.12	I-SECT	Master led main signal
J6.11	I-OPTOM	Motor rotation opto master control signal
J6.19	BUZ	Pilot buzzer command signal

2.1.2. Description of connectors

2.1.2.1. J1 mains connector

Pin	description
1	Neutral
2	Phase

2.1.2.2. J2 board / CPU connection

Pin	Description		
1	+ 5V controlled	power supply	
2	GND	power supply	
3	+ VBAT	power supply	
4	GND	power supply	
5	phase A	motor control	
6	phase B	motor control	
7	phase C	motor control	
8	phase D	motor control	
9	I signal	motor control	
10	BOOST signal	booster command	
11	sopt1	opto rotation module out put	
12	sopt2	opto anti-siphon module out put	
13	not in use		
14	cdopt1	opto rotation control module	
15	cdopt2	opto anti-siphon module control	
16	OFF	signal off key pressed	ON/OFF
17	SECT	mains power on signal power supply	
18	CDALIM	power cut signal	
19	LDSECT	mains LED control	
20	CTS	clear to send	
21	DEB/OFF	disengage signal active, set to 0	
22	RTS	request to send	
23	OCC/OFF	occlusion signal active, set to 0	
24	BUZ	nurse call relay control	
25	EOC	end of conversion ADC	
26	CSADC	selection bus SPI ADC	
27	CLK	clock bus SPI ADC	
28	SI	data IN bus SPI ADC	
29	SO	data out bus SPI ADC	
30	CDANA	analog sensor power control	
31	RX2	receive data TTL line 2	
32	TX2	transmit data TTL line 2	
33	TXD1	transmit data TTL line 1	
34	RXD1	receive data TTL line 1	
35	TOFF	OFF key	
36	TON	ON key	
37	+ VBAT	power supply	
38	GND	power supply	
39	+ 5V	power supply	
40	GND	power supply	

2.1.2.3. J3 potentiometric sensor connector

Pin	Description
1	VREF
2	centre point
3	GND

2.1.2.4. J4 internal battery connector

Pin	Description
1	battery **+**
2	battery **-**

2.1.2.5. J5 motor connector

Pin	Description
1	+ VBAT
2	+ VBAT
3	PHASE D
4	PHASE C
5	PHASE B
6	PHASE A
7	opto rotation anode diode/ + 5V
8	opto rotation cathode diode
9	opto rotation collector transistor
10	opto rotation transmitter transistor / GND

2.1.2.6. J6 rear panel connector

The connector on the rear panel concentrates signals from the external gauge bridge, the optional RS232 series link, the nurse call relay output and the configuration series link.

Pin	Description		
1	TX1	transmit data	line 1
2	+ 5V	power supply	
3	RX1	receive data	line 1
4	GND	power supply	
5	DTR	interface confirm	
6	APP-INF COM	nurse call relay common point	
7	APP-INF NO	nurse call relay normally open	
8	APP-INF NF	nurse call relay normally closed	
9	CD ON	external ON	
10	CD OFF	external OFF	
11	I-OPTON	motor control out put	
12	I-SECT	main led	
13	+ V BAT	external power plug	
14	RX 2	receive data line 2	
15	T X 2	receive data line 2	
16	GND	power supply	
17	CTS	clear to send	
18	RTS	Request to send	
19	BUZ	buzzer external control	

2.1.2.7. J7 external DC power supply connector

Pin	Description
1	External power +/-
2	External power -/ +

2.1.2.8. J8 pump ribbon cable connector

The pump ribbon cable connector concentrates all the signals from the sensors located in the plunger: disengage microswitch, gauge bridge and anti-siphon opto switch.

Pin	Description	
1	+ VREF	+ internal gauge bridge
2	E1	internal gauge bridge/occlusion input on
3	E2	internal gauge bridge/occlusion input off
4	GND	internal gauge bridge
5	C DOPT2	anti-siphon cathode diode
6	+ 5V	opto anti-siphon anode diode / + 5V
7	S OPT 2	opto anti-siphon collector transistor
8	DEB / ON	disengage microswitch on
9	DEB / OFF	disengage microswitch off
10	GND	

- Important: Disassemble the ribbon cable holder on the supply board before extracting the mechanical assembly from the lower housing.

2.1.2.9. J9 Test Points

Pin	Description
1	GND
2	out put position sensor
3	out put low battery control
4	out put force sensor amplifier
5	N.U.
6	out put optical switch motor control
7	force and position sensor voltage Ref.
8	out put optical switch syringe led detection

2.1.3. Electrical layout

(Refer to Annex 2)

2.1.4. Installation layout

(Refer to Annex 2)

2.2. CPU BOARD

Overview

The CPU board is fitted to Injectomat 2000 MC / Pilot Delta version, around a 80C32 microprocessor used in open mode. It concentrates all the peripheral devices directly connected to the 80C32 bus. It is connected to the power supply board by a 40 contacts ribbon cable and to the display board by fixed connectors. It forms a single unit, with the display board, which is fixed to the front panel.

The CPU board uses CMOS technology in order to minimise power consumption.

Current used: 5 Volts 80 mA maximum.

2.2.1. Functional description

The CPU board comprises six functional units:

- Ram rom decoding processor
- Reset WATCH DOG
- Parallel port extensions

display/keyboard interface,

motor interface,

sensor interface.

- SPI BUS
- Asynchronous serial link
- Optical sensor

2.2.1.1. RAM ROM decoding processor

Decoding is carried out by an IC3 80C32 circuit, running at 12 MHz, clocked by Q1. It is used in open mode, with the EA*/VP line connected to GND.
Address/data de-multiplexing is carried out by a 74HC573 U3.
On this BUS are implemented:

32 Ko static RAM		U6
27C040	512 Ko	U4

2.2.1.2. Reset watch-dog

The RESET WATCH-DOG module comprises two TL7705 U10 and U11 circuits.

Operation: the U10 circuit generates RESET signals, active at 1, for the processor and the UART; RST* active at 0 generates RESET signals for the other peripheral devices.
The signals are activate in two cases:

- when the system is powered up,
- as soon as the WATCH-DOG circuit is triggered. It remains active until the power is turned off.

2.2.1.2.1. Reset at power-up

The TL 7705 circuit guarantees the minimum duration of the reset lines, in the active state, once the + 5V voltage has exceeded the circuit operating threshold (4.75V). It returns to the active state, if the + 5V voltage drops below the threshold or if the RESTIN* (U11.2) is at 0. The line is driven by the WATCH-DOG module.

The duration of the reset, in the active state, at power-up is set by the C10 capacitor 220nF 100 ms.

2.2.1.2.2. Watch-dog

The WATCHDOG circuit comprises the following elements: U10, U11, C12, D2, D1, R4, C11.

When powered up the capacitor C12 is charged by the U10 circuit, via diode D1.
The charge is maintained at a threshold of over 1.5 V during operation.

The software writes, every 1 ms. This writing generates a 5V/1µs impulse on the U7.10 output, which recharges the capacitor C12 via a high pass peak detector circuit made up C8, D3, D2. The C12 capacitor discharges in resistor R4.

When the software stops, the capacitor C12 completely discharges. The U11 RESTIN* line falls to 0 and the RESET signals are activated, stopping all syringe-pump control operations in the inactive state. Fault signals, the blinking FAIL diode and the continuous BUZZER are stuck in an active state.

WATCH-DOG trigger time is less than 400 ms.

2.2.1.3. Keyboard/display interfacing

2.2.1.3.1. Display registers

The display system is made of LED's and of a 2 lines of 20 characters LCD graphic screen. The U7 circuit allows to address the matrix of the LED's, the U8 circuit allows the writing and reading in the display controller.

The LED's matrix are DIG0 to DIG7 and SEG0 to SEG7.

The FAIL LED shows the device is failed, the command is inverted to be active by default at RESET. It is active at 1 on the display board. The FAIL diode is out of the matrix to be able to light on when the microposssor does not work.

2.2.1.3.2. Buzzer

The BUZZER command is inverted and controls the transistor, T3, which is mounted as a common transmitter. Working in parallel, the transistor collector drives the BUZZER on the display board and the nurse call relay on the motor control power supply board. After starting the pump, the BUZZER is activated for added safety.

BUZZ signal: J5 pin 6 and J3 pin 24 50 mA 6.75 Volts maximum.

2.2.1.3.3. Keyboard register

The keyboard is based on a 6 x 3 matrix, with 2 separate keys - TON and TOFF - with 1 common point (GND). They turn power ON and OFF respectively and are connected to the display board. TON and TOFF signals only transits via the CPU board.

The columns of the keyboard are driven by the same signals as the columns in the display matrix, thus facilitating simultaneous keyboard and display monitoring. Register U15 reads the status of the three keyboard lines, LIG1, LIG2 and LIG3 in order to check whether a key has been activated.

2.2.1.3.4. Motor control register

The U12 motor control register generates 4 motor phase signals, A,B,C and D, the I current control signal, the motor rotation opto control CDOPT1 signal and the BOOST BOOSTER control signal.

2.2.1.3.5. Sensor status register

The U16 sensor status register reads the microswitch digital sensors and the syringe pump opto switch.

2.2.1.4. SPI bus EEPROM

The SPI bus is synchronous series communication bus using various peripheral circuits. The SPI bus is driven by the 80C32 ports.

The Injectomat 2000 MC / Pilot Delta syringe pump has 2 peripheral devices on the SPI bus:

- The EEPROM 16 Ko 24C128 U12 located on the CPU board.
- The MC 145053 analog/digital converter located on the motor board.

This bus has 2 communication lines: 80C32 (see electrical diagrams)

	Micoprocessor Ports	
CLK	clock generated by the microprocessor	P 1.1
SI	peripheral to processor data (input)	P 1.2

2.2.1.5. Asynchronous serial links

The Injectomat 2000 MC / Pilot Delta syringe pump is fitted with two asynchronous serial links.

RS232 option	line 1
TTL configuration serial link	line 2

2.2.1.5.1. RS232 serial link

The RS232 serial link is implemented using the U8 SCC2691 circuit, which controls asynchronous communication, and RS232 interface circuit which is located on the motor power supply board.

The circuit is clocked by quartz Q2 at 3.6864 MHz. It includes a programmable baud rate generator. It generates interrupts on the ITRS232 line connected to the processor at INTO.

The SCC2691 is on the microprocessor bus. It drives the RXD1 receive data signals on J3 (pin 34) and TXD1 transmit data signals on J3 (pin 35).

The RS232 option is reserved for dialogue with the host computer responsible for monitoring or controlling the system.

2.2.1.5.2. TTL serial link

The TTL serial link is driven by the serial link controller inside the microprocessor. It uses one of the internal timers to generate its baud rate, from the basis of the processor 12 MHz clock. The serial link drives the TXD2 transmit data and RXD2 receive data lines. The input and output lines are buffered by the U9 74HC14 buffer trigger inverter circuit.

The lines are available on J3.

TX2	J3	pin 33
RX2	J3	pin 34

This serial communication line is reserved for Injectomat 2000 MC / Pilot Delta software configuration and, when appropriate, for connecting an external MASTER module.

2.2.1.6. Opto switch sensors

Injectomat 2000 MC / Pilot Delta syringe pump opto switch sensors are for piston pressure and syringe body presence and motor rotation.

The syringe body opto switch interface is located on the CPU board. It is implemented using transistors T1, T2 and T3. Resistor R9 limits current in the diode to 8 mA.

2.2.1.6.1. Opto switch body syringe measurement.

- Note: The CI opto and the obturator are specific to the Injectomat 2000 MC / Pilot Delta equipped with "flange detector" and are not compatible with previous versions.

- 2 opto devices allow to detect 2 syringe sizes: 60 cc and 20 cc.

J2.1	opto diode +5V anode
J2.2	opto cathode common point and transistor transmitter
J2.3	opto 1 transistor collector
J2.4	opto 2 transistor collector

Control signal:	CODPT3	activate at 1	driven by microprocessor line T0.
Output signal:	SOPT4	activate at 1	register U16 D1 address $ C000
Output signal:	SOPT3	activate at 1	register U16 D0 address $ C000

.

	SOPT3	SOPT4
Syringe clamp detection alarm, high position	1	0
60 cc detection	1	1
20 cc detection	0	1
Syringe clamp detection alarm, low position	0	0

The motor rotation and piston presence opto switch interfaces are located on the POWER SUPPLY BOARD.

2.2.1.6.2. Motor rotation opto switch

Control signal:	CDOPT1	activate at 1
Output signal:	SOPT1	activate at 1

2.2.1.6.3. Piston presence opto switch (anti-siphon)

Control signal:	CDOPT2	activate at 1
Output signal:	SOPT2	activate at 1

2.2.2. Description of connectors

2.2.2.1. J1 not used

This connector is not used for the moment but it will be used for a future evolution of the software.

2.2.2.2. J2 Opto switch - syringe body connector

Pin	Description
1	ground
2	flange switch
3	opto +5 V diode anode
4	cathode diode transmitter transistor opto 1 and opto 2 common points
5	collector transistor opto 1
6	collector transistor opto 2

2.2.2.3. J3 Power supply/CPU ribbon cable

A 40 channel ribbon cable is soldered directly to J3, linking the power supply and the CPU.

Pin	Description		
1	+ 5V controlled	power supply	
2	GND	"	
3	+ VBAT	"	
4	GND	"	
5	A phase	motor control	
6	B phase	"	
7	C phase	"	
8	D phase	"	
9	I signal	"	
10	BOOST signal	"	
11	SOPT1	opto rotation module output	
12	SOPT2	opto anti-siphon module output	
13	APINF	nurse call independent from buzzer signal	
14	CDOPT1	opto rotation module control	
15	CDOPT2	opto anti-siphon module control	
16	OFF	ON/OFF key depressed signal	
17	SECT	mains power supply on signal	
18	CDALIM	power cut signal	
19	LDSECT	mains LED control	
20	CTS	Clear to send	line 2
21	DEB/OFF	disengage active at 0 signal	
22	RTS	Request to send	line 2
23	OCC/OFF	occlusion active at 0 signal	
24	BUZ	nurse call relay control	
25	EOC	end of conversion ADC	
26	CSADC	selection SPI ADC bus	
27	CLK	clock SPI ADC bus	
28	SI	data INSPI ADC bus	
29	SO	data out SPI ADC bus	
30	CDANA	analogue sensor power supply control	
31	RX2	receive TTL data	line 2
32	TX2	transmit TTL data	line 2
33	TXD1	transmit TTL data	line 1
34	RXD1	receive TTL data	line 1
35	TON	ON key	
36	TOFF	OFF key	
37	+ VBAT	power supply	
38	GND		
39	+ 5V		
40	GND		

2.2.2.4. J4 Display board interconnection

Pin	Description	
1	SEG1 display matrix	line 1
2	SEG2 display matrix	line 2
3	SEG3 display matrix	line 3
4	SEG4 display matrix	line 4

5	SEG5 display matrix	line 5
6	SEG6 display matrix	line 6
7	SEG7 display matrix	line 7
8	SEG8 display matrix	line 8
9	COL1 display matrix	column 1
10	COL2 display matrix	column 2
11	COL3 display matrix	column 3
12	diode FAIL control	
13	RDCRT current reduction control	
14	LIG1 keyboard interface	line 1
15	LIG2 keyboard interface	line 2
16	LIG3 keyboard interface	line 3
17	LDSECT	mains LED lighting control
18	+ 5V	power supply
19	VBAT	power supply
20	GND	power supply

2.2.2.5. J5: Display/CPU connection

Pin	**Description**	
1	TON	ON key
2	TOFF	OFF key
3	SI	SPI bus
4	CLK	SPI bus
5	CSLCD	bus
7	VBAT	power supply
8	GND	power supply

2.2.3. Electrical layout

(Refer to Annex 2)

2.2.4. Installation layout

(Refer to Annex 2)

2.3. DISPLAY BOARD

2.3.1. Overview

The display board is mounted directly beneath the front plate of the syringe pump. It brings together all the facilities for operator/device dialogue: Keyboard, buzzer and display.

It is connected to the CPU by rigid connectors, forming a sandwich, with the former, held in place by struts.

The soft keyboard is connected to the display board.

2.3.2. Functional description

The display board comprises four modules:

- The electroluminescent display,
- The keyboard interface,
- The liquid crystal display,
- The buzzer.

2.3.2.1. Electroluminescent display

The electroluminescent display is made of eighteen LED's and five 7 segment display units, with the decimal point, except two of them which are marked (*) in the table below.

The diodes and display units are driven in a multiplexed, 8 segments x 8 digit matrix. The LED's and display units are mounted with a common cathode.

The 8 segments are driven by signals SEG0 to SEG7 and the 8 digit by signals DIG0 to DIG7.

The 2 LED's, "MAIN PRESENCE" and "FAIL" are controlled independently of the matrix.

2.3.2.1.1. LED's table

The following table lists the various diodes used in different models.

Ref	Name	Type	Seg	Dig
LD1	Mains On	yellow	*	*
LD2	Body Alarm	red	1	0
LD3	Piston Alarm	red	2	0
LD4	ml	green	5	1
LD5	Battery	green	7	1
LD6	Fail	red	*	*
LD7	Alarm	red	4 to7	0
LD8	Worm screw 3	green	2	1
LD9	Prealarm	orange	1 to 4	2
LD10	Occlusion Alarm	red	0	0
LD11	Worm screw 2	green	3	1
LD12	Infusion End Alarm	orange	0	2
LD13	Worm screw 1	green	4	1
LD14	NU			
LD15	Connection to PC	green	0	1
LD16	disengagement alarm	red	3	0
LD17	ml/h	green	5	1
LD18	Battery Alarm	red	5	2
LD19	Validation Demand	green	1	1

2.3.2.1.2. Seven segment display units

Ref	Name	Type	Seg	Dig
U3	hundreds	green	0 to 7	6
U4	tens	green	0 to 7	5
U5	units	green	0 to 7	4
U6	tenths	orange	0 to 7	3
U2	thousands	green	0 to 7	7

2.3.2.2. Keyboard interface

The keyboard is an 18 key matrix keyboard. The keys are arranged in 3 rows of 6, with two separate keys with a common point (GND), TON and TOFF, and power on and off switches, connected to J2.

Ref	Digit	Ligne
SILENT	2	2
STOP	1	2
VALIDATION	0	2
PURGE	3	2
BOLUS	2	0
DECAL	4	0
SELINC	3	0
SELDEC	2	1
ENTER	3	1
HISTO	4	1

Description of the connector

J2. 1	DIG 5
J2. 2	DIG 4

J2. 3	DIG 3
J2. 4	DIG 2
J2. 5	DIG 1
J2. 6	DIG 0
J2. 7	LINE 0
J2. 8	LINE 1
J2. 9	LINE 2
J2. 10	TON
J2. 11	TOFF
J2. 12	GND

2.3.2.3. LCD display unit

The LCD display unit is "chip on glass" type, the controller is fixed on the glass. It has 2 lines of 20 characters.

The BUS gestion is multiplexed with the command of SEG0 and SEG7.

It has a double powered retrolighting.

The power supply of the LED pair, one by one, allows an optimum light for a minimum consumption.

2.3.2.4. The buzzer

The buzzer is an auto-exit buzzer supplied by VBAT.

It is driven by the BUZZ signal, available on connector J3, pin 6, which is generated by the CPU board. It is mounted in parallel with the optional nurse call circuit, located on the motor power supply board.

2.3.2.5. Time keeper

Real time device DS1307

2.3.3. Description of connectors

2.3.3.1. J2 Display board / CPU board connection

Pin		**Description**	
1	SEG0	display matrix and command LCD display	line 1
2	SEG1	display matrix and command LCD display	line 2
3	SEG2	display matrix and command LCD display	line 3
4	SEG3	display matrix and command LCD display	line 4
5	SEG4	display matrix and command LCD display	line 5
6	SEG5	display matrix and command LCD display	line 6
7	SEG6	display matrix and command LCD display	line 7
8	SEG7	display matrix and command LCD display	line 8
9	COL1	display matrix and keyboard	column 1
10	COL2	display matrix and keyboard	column 2
11	COL3	display matrix and keyboard	column 3
12	FAIL	diode FAIL control	Fail
13	RDCRT	display control writing command	
14	LIG1	keyboard interface	line 1
15	LIG2	keyboard interface	line 2
16	LIG3	keyboard interface	line 3
17	LDSECT LED	mains lighting control	LED sector
18	+ 5V	power supply	
19	VBAT	power supply	
20	GND	power supply	

2.3.3.2. J3 CPU board connection

Pin	**Description**	
1	TON	ON key
2	TOFF	OFF key
3	SI	bus SPI

4	CLK	bus SPI
5	CSLCD	bus SPI
6	BUZZ	BUZZER control
7	VBAT	power supply
8	GND	power supply

2.3.4. Power consumption

Main supply (without battery)		Battery supply (without main supply) measurement made on the battery	
0 ml/h	1200 ml/h	0 ml/h	1200 ml/h
31 mA / 230v ~	47 mA / 230v ~	< 125 mA / 6,0 VDC	700 mA / 6,0 VDC

2.3.5. Electrical layout

(Refer to Annex 2)

2.3.6. Implantation layout

(Refer to Annex 2)

3 Configurations

***Fresenius Vial* recommends the presence of its qualified personnel or of a trained member of the Technical Department of your establishment to help you implement the configuration procedures you wish to choose.**

Note: press STOP to cancel modification at any time - Press to leave configuration mode at any time.

3.1. Configuration of the pressure functionalities

Moving to the pressure configuration mode: press + : Pres appears on display.

Press	Configuration mode	Valid.	Choice	Press ▲ ▼ (⇄) to select	Valid.
▲ ▼	Pres 1 : variable threshold mode.	OK	Pres 1 900 mmHg	preset pressure limit at a value sets between 100 and 900 mmHg at power on or use the last programmed value (___)	OK
	Pres 2 :pressure limit by syringe capacity.	OK	50/60 ml syringes Pres 2 50 cc 800 mmHg	from 100 to 900 mmHg	OK
			20 ml syringes Pres 2 20 cc 600 mmHg	from 100 to 900 mmHg	OK
			Note: at any time, it is possible to press START key to store programmed values and resume Pres 2.		
	Pres 3 : pressure drop warning level.	OK	Pres 3 100 mmHg	from 50 to 1100 mmHg (disable this warning 0 mmHg)	OK

3.2. Configurations of the various parameters

Moving to configuration of the various parameters mode, press simultaneously + : Par appears on display.

Press	Configuration mode	Valid.	Display	Press ▲ ▼ (⇄) to select	Valid.
▲ ▼	Par 1 : preset parameters at power on. (parameters: flow rate, rate mode unit, drug name, drug concentration, patient weight)	OK	Par1	use last parameters preset parameters: flow rate: 00.0 ml/h	OK

				rate mode proposed :ml/h patient weight, V/T values : preset at last values before ☒ selection
	Par 2 : syringe selection type.	OK	Par2 SEL4	SEL3 only one syringe per capacity with automatic confirm SEL4 multisyringe mode
	Par 3: maximum flow rate selectable via the keyboard.	OK	50 ml syringe Par3 50 cc 800 ml/h	from 0.1 to 1200 ml/h
			20 ml syringe Par3 20 cc 550 ml/h	from 0.1 to 600 ml/h
	Par 4 : selectable syringes/syringe list restriction.	OK	BD Plastipak 50 cc ☒	☒ selectable syringe on display ☐ not selectable on display Selection for any syringe
	Par 5 : prime compulsory.	OK	Par 5 ☒	☒ priming compulsory ☐ no priming compulsory
	Par 6 : rapid infusion start up.	OK	Par 6 ☒	☒ running rapid infusion start up ☐ no rapid infusion start up
Press	Configuration mode	Valid.	Display	Press ▲ ▼ (⇄) to select
▲ ▼	Par 7 : KVO rate.	OK	KVO = 1.0 ml/h KVO = 2.0 ml/h	From 0.1 to 5 ml/h
	Par 9 : RS 232 baud rate.	OK	Par 9 19200	4800, 9600, 19200 Bauds
	Par A : empty syringe mode (finish on occlusion).	OK	Par A ☒	☒ activated ☐ disabled
	Par B : frequency of maintenance and date of next maintenance	OK	Par B 200 h 12/05/2000	from 1 hour to 9 999 hours of continuous use (preset at 3 000 hours) Note : select 0000h to desable
			Par B 200 h 12/05/2000	Select date and shift to next item by pressing OK key. Note : select 00/00/0000 to desable date of next maintenance mode
				Note: at any time, it is possible to press START key to store programmed parameters and resume Par B.
	Par C : drug library (see page 9)	OK	ADRENALIN 200ng/ml	Drug library configuration
	Par D : syringe flanges detection.	OK	Par D ☒	☒ activated ☐ disabled
	Par E : pre-programmed bolus dose rate and volume preset value at power on	OK	Par E ☒	☒ use the last rate and volume settings ☐ used a preset fixed value for rate volume = 0.1 ml
		Preset fixed value	50 ml syringe Par E 50cc 800.0 ml/h	From 50.0 to 1200.0 ml/h
			20 ml syringe Par E 20cc 600.0 ml/h	From 50.0 to 600.0 ml/h
	Par F : bolus rate value at power on	OK	Par F ☒	☒ use the last set rate setting

			☐ used a preset fixed value	
	Preset fixed value	50 ml syringe Par F 50cc 800.0 ml/h	From 50.0 to 1200.0 ml/h	OK
		20 ml syringe Par F 20cc 600.0 ml/h	From 50.0 to 600.0 ml/h	OK
Par G : rate mode selection	OK	Ml/h ☒	Activate or disable rate mode with ▲ ▼. Shift to the next item by pressing OK OK key ☒ activated ☐ inhibited	
Par J : mains disconnection warning inhibition.	OK	Par J ☒	☒ inhibited ☐ mains disconnection warning active	OK
Par P : name of the service	OK	Par P ICU 15210 ____	Select the service name	OK

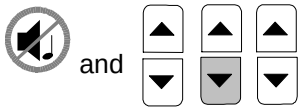
Important: measurements of the friction forces on the plunger stoppers do not show stable characteristic. For this reason, we recommend not to use Star mode (Par6).

3.3. CHECKING THE PILOT

N.B.: the tests outlined below do not include the occlusion tests, the flow rate tests, the electrical safety tests, etc.

3.3.1. The After Sale Service test

The ASS test is activated by pressing simultaneously on the keys:



and

until following display:

The validation LED flashes.If START is not pressed, within 3 seconds, the device returns to normal running.

The device display, for example:

The keys , and START allows to scroll in the following list:

"TEst.1" = displays running time with zero reset if necessary and service date modification

"TEst.2" = tests all indicator lights (LED's, 7-segment display unit AND LCD screen)

"TEst.3" = tests keyboard.

"TEst.4" = displays battery voltage

"TEst.5" = displays code of last 10 alarms.

"TEst.6" = displays total running time.

"TEst.7" = TTL serial link test.

"TEst.8" = RS232 serial link test.

"TEst.9" = displays force on plunger.

"TEst.A" = software version, check sum, loading date and language.

"TEst.B" = displays ADC analog inputs.

"TEst.C" = displays driving block position.

"TEst.E" = displays calibration values.

"TEst.F" = displays calibration syringe type.

"TEst.J" = displays of the last 10 events before the last blocking error.

"TEst.L" = drugs library.

3.3.2. Running time tESt.1

This test allows to display, first, the running time in hours, days and months.

Press on START gives the maintenance date. This date may actualised with the key board.

3.3.3. Lights test tESt.2

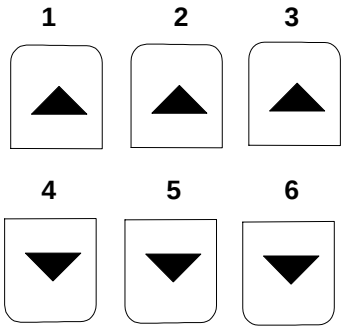
This test allows to check the lighting of LED's of the front panel, of the 7 segments display and of the LCD screen. First, all the items light at the same time and then light one after another.

This test can be stopped at any time by pressing STOP

3.3.4. Key board test tESt.3

This test allows to test the correct functioning of every key. The message "Test 3" is permanently displayed. When pressing on a key, its name displayed on the screen

	OFF	Switch off
	SIAL	Alarm silent / Information keys
	STOP	Stop infusion
	START	Validation (note: pressing longer than 2 seconds on this key, drives back to tests choice)
	BOLU	Bolus manual control
	DECAL	Moving the traveller
	INC	Increase
	DEC	Decrease
	OK	Enter, validation
	OPT	Options menu



1 : INC +++

2 : INC ++

3 : INC +

4 : DEC +++

5 : DEC ++

6 : DEC +

Nota: ⊙ ON, can't be tested

If several keys are pressed simultaneously, the device displays "Err" and gives an alternative "BIP".

The ○ key works normally: the message "**OFF**"is displayed as soon as pressed, the device is switched off if pressed more than one second.

3.3.5. Battery voltage display tESt.4

This test displays the battery voltage over 5 digits. The voltage is calculated in accordance with corresponding analog input value and calibrating values. The values used are those for escape from an alarm or pre-alarm (6.3 V) or starting an alarm (5.7 V).

The display is in volts and tenths of volts. The display is continuously updated according to the voltage changes.

The battery and mains LED's are also updated. The battery LED begins to flash if the voltage displayed is below the calibrated pre-alarm threshold and stops flashing if the voltage is above the pre-alarm output threshold.

Press the CONFIRM key to select another test.

3.3.6. Last 10 alarms codes tESt.5

This test displays the codes of the last 10 events on the display units. Three types of events are memorised :

- ALARM
- ERROR
- SWITCH OFF: two cases

Normal SWITCH OFF by pressing the OFF key.

Abnormal SWITCH OFF due to misfonctioning.

When an alarm goes off, an "A" is displayed followed by a number identifying the alarm:

Alarm	Description
10	battery
11	syringe clamp
12	end of infusion
13	volume limit
14	disengagement
15	plunger head
16	occlusion
25	Flange
26	Main line disconnection

In case of error, an "**E**" is displayed followed by error number:

Error	Description
01	rotation control
03	communication
32 / 52 / 72 / 82	segment advance check
44	CPU / UART frequency control
50	ADC access self-test
52	advance check during take-up
14 / 60	checking coherence of syringe parameters (incoherence of the syringe diameter in relation to the number of motor steps for 0.1 ml calculated when the syringe is confirmed)
70	incorrect motor frequency (motor step period too big or too small, calculated from the syringe diameter and the selected flow rate)
72	advance check over the whole length
80	important electromagnetic interference's or bad key board.
16 / 55	Time keeper
18	Max infused (1,7l) reached
28	Language file error
24 / 34 / 44 / 56	Software error
66	LCD error

The error codes: 10 (internal Ram self-test(+)
20 (external Ram self-test(+)
30 (EEPROM check-sum self-test) and
40 (EEPROM access)

These errors cannot be stored in the EEPROM; the running of the device is too pertubated to allow it to write in the EEPROM.
When normally stop, the "OFF" message is displayed.
For abnormal stop "OFF" + flashing "F" (Fail) are displayed on the LCD screen.
The events are numbered from 0 to 9. 0 is the last event, 9 is the eldest one.

The keys and allows to scroll the events one way or the other

Example:

Means: event N° 8 was a type 01 error (rotation control)

3.3.7. Total running time tESt.6

Use this test to display the total running time of the Pilot. Unlike "Test 1" which resets the time at zero when the service date is modified, it is not possible to modify this time manually.

Example:

3.3.8. TTL Serial link test: tESt.7

This test allows to verify the TTL serial link TTL (80C32), by placing a plug on which the Rx and Tx lines are " short-circuited "(pin 2 and 3).

If link is correct: **LTOK** is displayed

If link is not correct or if plug is not connected: **LTER** is displayed

3.3.9. Serial link test: tESt.8

This test allows to verify the RS 232 serial link (2691), by placing a plug on which the Rx and Tx, RTS and CTS, DSR and +5 V lines are "short-circuited" (pin 2 and 3), (7 and 8),(4 and 6)

LROK = RS 232 correct link.

LRER = break between Tx and Rx

NORC = - break between RTS and CTS,

- break between DSR and + 5 V
- no plug

3.3.10. Strength on the plunger display: `tESt.9`

This test displays the strength applied on the plunger. The strength is calculated according to the value of the corresponding analogue input and the calibrating values. The display is in grams. The value is continually updated according to changes in the strength value.

3.3.11. Software version `tESt.A`

This test allows to display the software number version, the check sum and the loading date.

Press on OK allow to display the language.

Example:

1rst screen

2nd screen

Press on ▲ ▼ for other language screen

3.3.12. Analog input display `tESt.B`

This test allows to read the hexadecimal value of the 5 analogic inputs and of the 3 converter test inputs. The channel number is displayed above this value.

Example

The keys ∧ and ∨ allows to pass from one channel to an other.

The analogue inputs are divided as follows:

0	battery voltage
1	N.U.
2	force sensor
3	NU
4	potentiometer displacement

L	converter zero test, between 0000 and 0004 if correct
M	converter mid-scale test, between 01FB and 204 if correct
H	converter full-scale test, between 03B and 3FF if correct

3.3.13. Driving block position display tESt.C

This test displays the position of the driving block. The position is calculated in relation to the value of the corresponding analogue input and calibrating values. The display is in mm and tens of mm. The value is continually updated as the driving block moves. The value displayed is ± 0,1 mm.

3.3.14. Calibration values display tESt.E

This test allows to show the calibration values stored in the EEPROM.

Every value is displayed on 3 digits.

The first line gives the shorted name of the value.

Example:

The keys and allows to pass from one channel to an other.

bat1	alarm and pre-alarm battery voltage: 6.3 V
bat2	pre-alarm battery voltage: 5.9 V
bat3	alarm battery voltage: 5.7 V
HIGH	displacement potentiometer with large 115.0 mm spacer
LOW	displacement potentiometer with small 20.0 mm spacer
0G	force meter with 0 kg
5Kg	force meter with 5 kg

3.3.15. Syringe type display tESt.F

This test displays the type of syringe fitted to the Pilot. The type is defined with the indications given by the optos of the syringe clamp.

The type of syringe is displayed with its capacity: 20cc (20/25cc), 50cc (50/60cc). The capacity may not be displayed if the parameters in EEPROM indicate that certain types of syringes are not included. When the syringe clamp is in the higher and the lower position 4 dashes are displayed.

The display is constantly updated in relation to changes in the syringe clamp system.

3.3.16. Displays of the last 10 events before the last blocking error tESt.J

This test allows to display the 10 last events before the last blocking error.

3.3.17. Drug library tESt.L

This test allows to read the name, the author and the date of the protocol library registered in the device.

4 REPLACING SUB-ASSEMBLIES

- Important: Disassemble the flexible circuit holder on the supply board before extracting the mechanical assembly from the lower box.

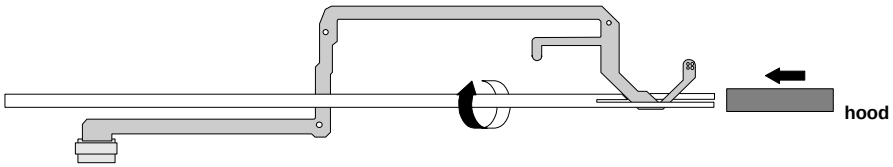
- Important: Device operation must be completely checked after all intervention inside the device.

4.1. Mounting the flexible circuit

- ❑ Important: Handle the flat cable with great care when mounting this sub-assembly: damage to the flat cable will result in complete disassembly of the mechanical block.

Fitting the flat cable

1. Take the flat cable and, using the "flat cable insertion" tool, wind the flat cable on the opposite side to the 10-point connector in the tool slot, keeping the flat cable tightened, wind it onto the equipment.



2. Take the black hood of the flat cable insertion equipment and position it on the wound flat cable part.
3. Insert the driving block cover and the input bearing on the diam. 12 tube, in the proper direction for mounting the various components.

Important: The input bearing flange must be placed on the side external to the driving block cover.

- ❑ Visually check that the "input bearing + driving block cover" are properly mounted on the tube.

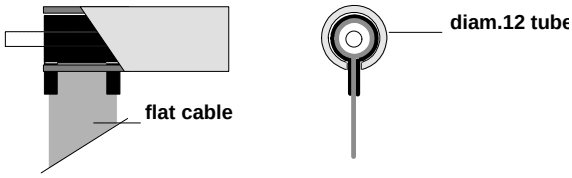
4. Insert the "flat cable insertion" tool in the diam. 12 tube on the input bearing side.

- ❑ The perpendicular flat cable parts are placed in the slits found at the ends of the tube.

5. Remove the black hood and the flat cable insertion equipment.
6. Correctly position the flat cable in the two slits visible at each end of the tube.

Important: The flat cable must not be twisted inside the tube.

7. Place the flexible circuit guards at both ends of the tube, passing the flat cable between the two holding lugs
8. Place the diam. 12 tube on the driving block making match the indexing finger of the driving block with the hole of the tube (opposite side of the 10 point connector)



9. Match up the flexible circuit hole with the driving block holder centring tube.
10. Secure the clamping collar onto the driving block using two 2.5 x10 screws and two washers.

4.2. Wiring the components on the flexible circuit

- ❑ Important: it is essential that the component mounting direction be respected.

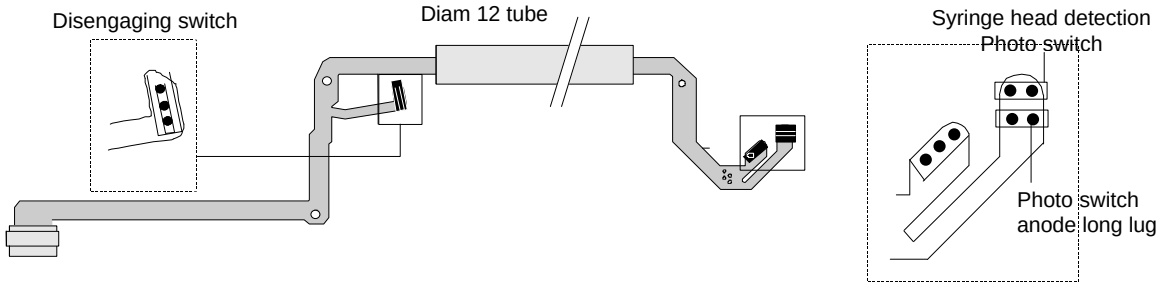
1. Position the strut (1.5mm) between the 4 pin photo switch and weld the syringe head detection photo switch flattening it against the flat cable.

Important: use a silicone between the optical switch and the flat ribbon cable. The silicon should not be over the soldering area.

Important: verify there is no resistor continuity between the optical switch axis stop and the flat ribbon cable.

2. Weld the disengaging switch flattening it against the flat cable.(at roughly 1.5 mm).

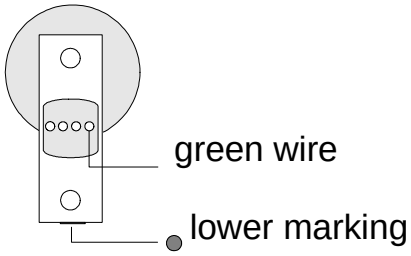
3. Cut the part of the flat cable corresponding to the back pressure microswitch of version A2 (see cutting zone in the diagram below).



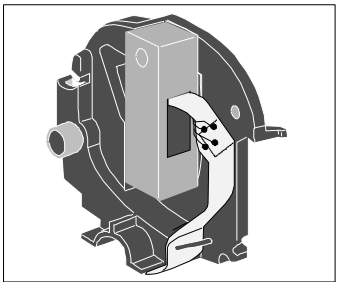
Weld the disengaging microswitch without flattening it against the flat cable (at roughly 1.5 mm).

4. Weld the force sensor wires

Important: when disassembling a force sensor, take care not to damage the welding pellets.



5. Pass the flat cable in the force sensor oblong.



Important: When disassembling the flexible circuit from the driving block holder, take care not to detach or damage the holder protection square. The purpose of this square is to hold the flexible circuit correctly in place and avoid short-circuits with the holder.

6. Mount the force sensor on the driving block holder using a TF HC M4x10 screw with weak lactate.

Important: avoid all contact between the force sensor and its holder.

7. Mount the contact plate on the force sensor using a TF M4x10 screw with weak loctite.

Important: Before calibrating the force sensor, adjust the threshold voltage (0.6V $\pm$ 0.05V) using an oscilloscope between pin 1 (earth) of J09 and pin 4 of J09 (square pulse).

Important: The device must be in the calibration mode (EtA9), obtained by simultaneously pressing the SILENCE ALARM key, the bolus key and the "ON" key.

8. Check that the amplitude of the square pulse increases when a manual force is exerted on the force sensor. When the force is removed from the sensor, the signal must return to the initial position.

Otherwise, check that the sensor is correctly mounted (sensor/holder friction).

4.2.1. Mounting the potentiometer

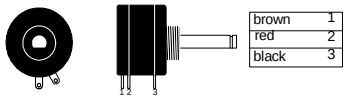
1. Disassemble the reducer flask end shield.

2. Mount the potentiometer on the flask (take the nut on a thread).
3. Position the flask in equipment T 300 869 and lock it in place using the knurled screw.
4. Position the potentiometer in the equipment and bring it up against the end shield.
5. Tighten the potentiometer.
6. Extract the flask from equipment T 300 869.
7. Mount the pinion on the potentiometer (match up the indexing half flat).
   - ❑ The pinion large diameter must be flattened against the potentiometer.
8. With the potentiometer facing you, turn the pinion in an anticlockwise direction until it blocks, then turn it 1/4 of a turn in the opposite direction.
9. Mount the moving mechanical assembly on the reducer frame.
10. Insert the flask on the guides and rack.
    - ❑ Check the position of the input bearing which must be on the driving block side.
    - ❑ Important: Take care not to damage the flexible circuit when mounting (folding).
11. Secure the end shield using the three M3x3 TC screws.
12. Secure the input bearing using the two M3x3 TC screws.

4.2.2. Wiring the potentiometer

1. Weld the 3 wires perpendicular to the lugs by placing them in the holes.

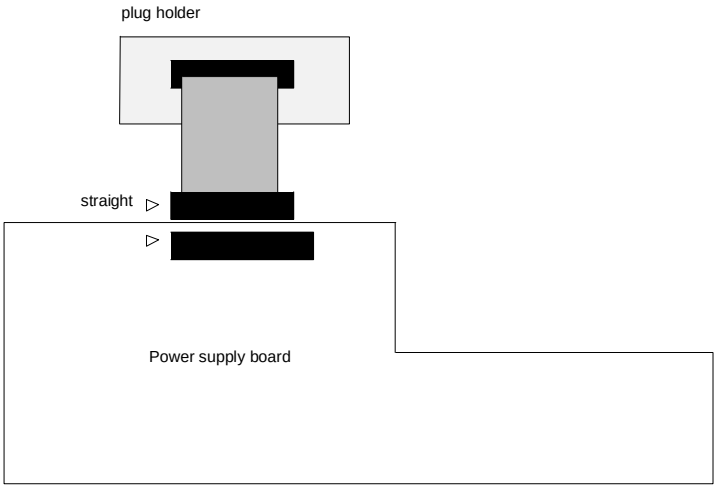
Important: Do not fold the potentiometer lugs



2. Mount the pinion and the potentiometer matching the indexing half flat with the small diameter of the pinion towards the potentiometer.
3. Mount the pinion hocking diameter 4 Truarc ring using a pair of flat mose fliers bearing down on the potentiometer shaft half flat.
4. With the pinion facing you, turn the potentiometer anticlockwise until it blocks, then turn it 1/4 of a turn in the opposite direction.
5. Disengage the moving assembly and slide it until it blocks against the reduction gear flange.
6. See `EtA6` calibrating test for the calibration of the potentiometer (section 3.2.2.).

4.2.3. Plug holder connector

If the total pins on the plug holder connector does not correspond to the total pins on the power supply board connector, the connecting method should be done as follows:



4.2.4. Lubricating the mechanical parts

NOTE: Use silicon grease exclusively.

Parts to be lubricated:

The two mechanical block guide rods

The screw rod

The top of the rack at guide level

The full length of the rack teeth

The disengaging spring housing in the 1/2 nut

The inside of the mechanical block.

5 MAINTENANCE

5.1. Recommendations

The qualified technicians in your establishment or our After-Sales Service should be notified of any abnormal operation of the device.

For further information concerning troubleshooting or usage procedure, please contact our After-Sales Service or our Commercial Department. (see Useful Addresses, chapter 10).

If the device has to be returned to our After-Sales Service, it must be packed very carefully, if possible in its original packaging before being sent.

FRESENIUS VIAL is not liable for loss or damage to the device during transport to our After-Sales Service.

5.2. Cleaning and disinfection

The syringe pump forms a part of the patient's immediate environment. It is advisable to clean and disinfect the device's external surfaces on a daily basis, in order to protect patient and staff.

- ❑ Disconnect the power cable from the wall socket before commencing cleaning.
- ❑ Do not place in an AUTOCLAVE, nor IMMERSE the device, and do not allow liquids to enter either the device's casing, or it's power supply cover.
- ❑ Use a cloth soaked in DETERGENT-DISINFECTANT, previously diluted with water if required, to destroy micro-organisms
  - Avoid abrasive scrubbing which could scratch the casing.
  - Neither rinse, nor wipe surfaces.
- ❑ If the device is located in a high contamination risk unit, it is advisable to leave it in the room during aerial disinfection, after having disinfected it in using a moist cloth.
- ❑ Do not use:
  - TRICHLOROETHYLENE-DICHLOROETHYLENE,
  - AMMONIA,
  - AMMONIUM CHLORIDE,
  - CHLORINE and AROMATIC HYDROCARBON,
  - ETHYLENE DICHLORIDE-METHYLENE CHLORIDE,
  - CETONE,
  - BASED CLEANING PRODUCTS.
- ❑ These aggressive agents could damage the plastic parts and lead to apparatus malfunctions.
- ❑ Take care with ALCOHOL BASED SPRAYS (20-40% alcohol); They lead to tarnishing of, and small cracks in, the plastic, and do not provide the requisite cleansing action prior to disinfection.
- ❑ Please contact the appropriate service, handling cleaning and disinfection products within your establishment, for further details.

5.3. Storage

In the case of prolonged storage time, disconnect the battery through the battery door located below the PILOT. This operation should be made by a fully competent technician.

Storage place should be dry and temperate.

- ❑ Temperature between 0 and 40°.
- ❑ Maximum relative humidity 85%, no condensation.

After storage, a full recharge of the battery is recommended before putting the syringe pump into use, in order to avoid any risk caused by micro power cuts in the mains supply and to insure maximum autonomy.

5.4. Routine inspections

In order to ensure an optimal functioning of the device, regular servicing inspections and tests are recommended every 24 months. A servicing procedure should include the points listed below. These service checks are not covered by any contract or agreement with FRESENIUS VIAL and are under the responsibility of user's technical staff. For further information, please contact our After-Sale-Service.

- ❑ NOTE: Incorrect servicing inspections may cause wrong functioning of the PILOT.

5.4.1. Checking before use

(see Operator's guide)

5.4.2. Checking protocol (Technical manual)

In order to ensure that the device is functioning optimally, regular servicing inspections and tests are recommended every 24 months.

A servicing check procedure should include the points listed below.

For further information, please contact our After-Sales Service.

The following servicing tests must be performed in accordance with the instructions defined in the Technical Manual.

- ❑ Note: Failure to comply with these maintenance procedures could damage the device and lead to functional failures.

5.4.2.1. Checking the syringe clasp detection arm

You have the tool test T301521-B.

1. Start the device by pressing the ON key.
2. Place a syringe plunger head, (take off the plunger from the syringe body) under the anti-siphon arm to stop the syringe plunger head detection alarm.
3. Pull the syringe clasp to the higher position and press the flange detection switch.
   - ❑ Ensure the syringe head alarm is present.
3. Place the tool reference T301385B with the clasp on the biggest diameter, then move the tool to check the 4 diameters
   - ❑ For the 2 biggest diameters, the Injectomat 2000 MC / Pilot Delta should display 50 ml capacity.
   - ❑ For the 2 smallest diameters, the Injectomat 2000 MC / Pilot Delta should display 20 ml capacity.
4. Take off the test tool, then place the syringe clasp in lower position and press on the flange detection switch
   - ❑ Ensure the syringe clasp alarm is present.

You do not have the tool test T301521-B.

1. Start the device by pressing the ON key.
2. Place the syringe clamp in open position and press the flange detection switch.
   - ❑ Ensure the syringe clasp alarm is present.
3. Place and clamp with the syringe clasp, every syringe type of the list registered in the PILOT
   - ❑ Ensure right detection for each syringe capacity
4. Take off the syringe then place the syringe clasp in low position and press on the flange detection switch
   - ❑ Ensure the syringe clasp alarm is present.

5.4.2.2. Checking the flange detection system

1. Start the device by pressing the ON key.
2. Place a syringe in the Injectomat 2000 MC / Pilot Delta and clamp it with the clasp.

Ensure right detection of the syringe.

3. Place a syringe on the Injectomat 2000 MC / Pilot Delta with flange OUT of the provided slot. Put on the syringe clasp.

Ensure the syringe clasp alarm is present.

5.4.2.3. Checking anti-siphon arm

- ❑ NOTE: this check should be done for every type of syringe registered on the PILOT

1 Start the device by pressing the ON key.

2 Place and clamp a syringe in the Injectomat 2000 MC / Pilot Delta with the clasp and pull the drive into maximum forward position to be sure the drive is not in contact with the head of the syringe.

3 When anti-siphon arm is in low position:

- ❑ Ensure plunger head presence detection alarm is present.

4 When anti-siphon arm is in high position:

- ❑ Ensure plunger head presence detection alarm is present.

5 For one of the registered syringes, correctly placed (clasp and drive in good position)/

- ❑ Ensure plunger head presence detection alarm is absent.

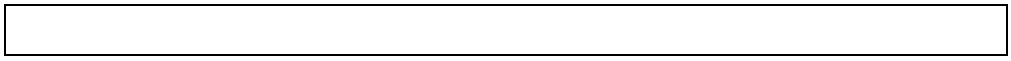
6 Pull the anti-siphon arm to check it is correctly fixed.

NOTE: If anti-siphon arm is dismounted, use stop-screw-glue when remounting.

5.5. Technical check procedure PILOT anaesthesia 2

For preventive maintenance, periodical check is recommended. Use the technical manual for good running of the procedure.

NOTE: Make a full battery charge (16 hours) before starting check procedure.



5.6. Checking disengagement system

1.Start the device.

2.Place a 50/60 ml syringe in the PILOT

3.Activate the disengaging lever.

- ❑ Ensure an acoustic and visual alarm is present.

4.Maintain the disengagement lever in high position and move the driving block

- ❑ Check easy driving block displacement (manual displacement).

5.Release the lever

- ❑ Ensure there is no alarm.
- ❑ Check driving block locking.

5.7. Checking force sensor

1. Proceed to test 9 (see section 3.3: checking the PILOT)
2. Use the disengagement system to pull the pusher backward so no force is applied to the sensor.
   - ❑ Displayed value should be between 0 and 100 g
3. Press and release the force sensor
   - ❑ Displayed value should be between 0 and 100 g
4. Apply a known force (about 5 Kg) on the pusher.
   - ❑ Displayed value should be 5 Kg +/- 250g.

5.8. Checking back-pressure

NOTE: The Injectomat 2000 MC / Pilot Delta initiates the sensor after pusher engagement. When testing back-pressure, the infusion should be started with no pressure on the line.

1. Start the device by pressing the ON key.
2. Place a manometer (or any other pressure measuring instrument) at the syringe outlet.
3. Select BD 60 ml Syringe.
4. Select the Medium Limit Pressure by pressing the LIMIT PRESSURE key.
   - ❑ M = (medium limit pressure) = 500 mmHg +/- 75 or 0.65 bar ± 0.1 bar.
4. Select maximum flow rate
5. Start the infusion (press START/CONFIRM).
   - ❑ Ensure there is no acoustic and visual alarm (back-pressure Led off),
   - ❑ Check infusion indicators are flashing.
   - ❑ Check visual and acoustic alarm for a 500 mmHg +/- 75 or 0.65 bar ± 0.1 bar pressure.

NOTE: If the pressure value measured according to the selection made falls outside the reference values, refer to the "EtA9 " calibration test (see Chap.3.2.3.).

NOTE: Before calibrating the force sensor, check the voltage between point J09.1 (earth) and J09.4 using an oscilloscope. Voltage value = 0.6 V + 0.05 V (square pulse).

5.9. Checking registered syringe list /syringe list label.

This test allows to check if the list of syringes registered in the Injectomat 2000 MC / Pilot Delta is in accordance with the list printed on the label.

Proceed to **H** test (section 3.3: **CHECKING THE PILOT**)

5.10. Checking Mains/Battery operation

1. Connect the device to a mains supply and check the presence of the mains Led (permanent yellow LED on).
2. Disconnect the device from the mains.
3. Connect the device battery lugs to a stabilised supply set at 6.3 V.

Important: Respect the +/-" polarities.

4. Place the device in the normal operating mode.
5. Select a syringe (from the syringes proposed by the PILOT) and validate.
6. Select a flow rate and validate.
7. Set the voltage on the stabilised supply between 5.8 V. and 6 V.

   - ❑ The battery discharge pre-alarm is activated

NOTE: The acoustic alarm can be temporarily silenced (2 minutes) by pressing the SILENCE ALARM key.

8. Turn down the voltage of the stabilised supply.

Check the battery discharge prealarm is activated between 5.6 and 5.8 Volts.

NOTE: If the values indicated above are not respected, refer to the "EtA4" test (Section: 3.2.1).

5.11. Checking linearity

Carry out this test to check the displacement of the driving block for a 50/60 ml B-D Plastipak syringe at a flow rate of 50 ml/h. Any non-correspondence between the value measured and the table value indicates a mechanical and electronic failure which could cause flow rate errors.

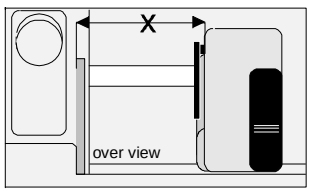
A checking software ISCTRL allow to carry out this test automatically (call FRESENIUS VIAL After-Sale- Service for further information)

5.11.1. Equipment used

- ❑ Stop clock
- ❑ Electronic calliper
- ❑ 50 ml B-D Plastipak syringe

5.11.2. Operating mode

1. Switch the device on by pressing on the ON key.
2. Place a 50/60 ml B-D Plastipak syringe on the device.



3. Measure the distance X (in millimetres) as shown on the diagram -> X_1
4. Select a 50 ml B-D Plastipak syringe.
5. Select a flow rate of 50 ml/h.

6. Start the infusion by pressing on the CONFIRMATION key and start the stop clock at the same time.

7. Stop the infusion after 50 min, then measure X again -> X_2

8. The displacement $X= X_1 - X_2$, in mm, must comply with the values indicated below.

Table of "distance X" displacement measurements

NOTE: For precise measurement avoid any movement of the pusher during measurement.

Time		Displacement in mm, for a flow rate selection of 50 m		
minutes	seconds	minimum	Average	Maximum
50	00	74.96	75.72	76.47
50	30	75.71	76.47	77.24
51	00	76.46	77.23	78.00
51	30	77.21	77.99	78.77
52	00	77.96	78.74	79.53
52	30	78.71	79.50	80.30
53	00	79.46	80.26	81.06
53	30	80.21	81.02	81.83
54	00	80.95	81.77	82.59
54	30	81.70	82.53	83.35
55	00	82.45	83.29	84.12
55	30	83.20	84.04	84.88
56	00	83.95	84.80	85.65
56	30	84.70	85.56	86.41
57	00	85.45	86.32	87.18
57	30	86.20	87.07	87.94
58	00	86.95	87.83	88.71
58	30	87.70	88.59	89.47
59	00	88.45	89.34	90.24
59	30	89.20	90.10	91.00
60	00	89.95	90.86	91.77
60	30	90.70	91.62	92.53
61	00	91.45	92.37	93.30
61	30	92.20	93.13	94.06
62	00	92.95	93.89	94.83

- **Important**: if the distance measured does not correspond to the value indicated on the table refer to "EtA6" Calibration mode.

5.12. Checking end of infusion

5.12.1. End of infusion pre-alarm

1. Start the device.
2. Select a 60 ml B-D PLASTIPAK syringe, 20 ml full.
3. Select a flow rate of 120 ml/hr.

   - For normal flow rates, the end of infusion pre-alarm is activated 5 minutes before end of infusion.

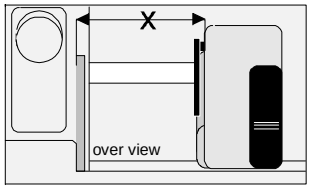
   - For higher flow rates (50 ml/hr), the pre-alarm is activated when the volume remaining to be infused equals 10% of total syringe capacity.

4. Ensure the end of infusion pre-alarm is present.
5. Press the SILENCE ALARM key to silence the acoustic alarm and check the end of infusion alarm (see in 5.4.2.7.2.).

5.12.2. End of infusion alarm

1. At the end of infusion:

- Check the acoustic and visual end of infusion alarm.



2. Measure the " hard height ": X, with 18.6 < X < 19.5 for a 50 ml B- D PLASTIPAK syringe.

- **Important**:
  For accurate checking of the hard height, do not move the driving block when measuring.

3. If X value is out the tolerated ones see " **Eta6**", section 3.2.,CALIBRATION.

5.13. Checking the Led's and keyboard

Refer to `tSt2` and `tSt3` (see section 3.2.: CALIBRATION)

5.14. Battery autonomy test

1. Medium battery autonomy is 7 hours (minimum 5) when the device operates with a 50 ml B-D PLASTIPAK syringe at a flow rate of 5 ml/hr (without Master module connection type)

2. The battery discharge pre-alarm warns the user the remaining autonomy is roughly 60 minutes (at 5 ml/h) before infusion will completely stop (total battery discharge alarm).

3. Battery recharging time is 16 hours minimum (100% of its capacity).

5.15. Continuity test

Using an multimeter connected ohmmeter, check the presence of an infinite electrical resistance between:

- phase and metal tube,

- neutral and metal tube.

5.16. Trouble Shooting

Problem	Causes
• Perfusion end detected too early (about 10 ml). • No occlusion prealarm and alarm at perfusion end. Major variation in flow rate or displacement control.	• Syringe used does not fit to selected one. • Syringe used does not fit to selected one. • Syringe used does not fit to selected one.
• Occlusion alarm when switching on.	• Bad calibration of strength sensor. • strength sensor out of order. • Cut in flexible circuit.
• Occlusion alarm when working.	• Pressure limit selected too low. • Bad calibration of strength sensor.
• Disengagement alarm when switching on.	• Disengagement microswitch out of order.
• Detection syringe piston unsuitable alarm.	• Opto sensor and/or obturator of syringe piston out of order.
• Syringe barrel holder unsuitable alarm.	• Opto sensor and/or obturator of syringe holder out of order.
• Syringe flange detection unsuitable alarm.	• Flange detection switch and/or connectic out of order.
• Bad display : segments or LED's.	• Driving transistors and/or connectic of display board out of order.
• Alarm without error code.	• Wrong power supply (6,9V) See MAX 652 • Bad CPU board.
• In case of drop…..	• Check mechanic set and centring of diameter 12 tube See exploded view.

5.17. Error message Er(-)0, Er01, Er(-)2, Er03, CFPc

Error code	Error code definition	Cause
ER (-) 0 Device self test on start up was not successful Er10 Er20 Er30 Er40 Er50 Er60 Er70 Er80	Electronic control + software anomaly Internal RAM anomaly External RAM anomaly EPROM anomaly Eeprom anomaly ADC anomaly Syringe parameters anomaly Motor frequency anomaly Keyboard anomaly	Check Sum: faulty RAM, EPROM, EEPROM When rewriting EEPROM on switching off the device the Check Sum is re-written in the memory to save the parameters. ❒ If the Hard cutoff circuit time is shorter than the Soft circuit time, the device is switched off before EEPROM is fully written: Check Sum not conform ❒ Er(-)0 or CFPc: When the device is in CFPc reconfiguration is compulsory: faulty WATCH DOG Faulty keyboard or short circuit in the keyboard or excessive electromagnetic interference.
ER0 1 Problem detected in motor control mechanism or in the motor itself.	Motor supply failure	Motor rotation photo switch + associated circuits brake.
ER(-) 2* Plunger advance checking has detected a error greater than the acceptable one (+)-) from 1 to 7: info: A.S.S. Er32 Er52 Er72 Er82	Mechanical advance checking anomaly Short distance anomaly Slack adjustment anomaly All length anomaly Flow rate anomaly	Potentiometer or ADC Often connector calibration or position potentiometer unscrewed
ER(-)4 Possible misfonctioning Er14 Er24 Er34	Motor and flow rate calculation parameters anomalies Motor period calculation anomaly Motor rotation direction anomaly Flow rate / period calculation anomaly	Functioning or configuration wrong parameters
CFPc The device self-test on configuration was not satisfactory	Configuration anomaly	Erroneous parameters.

5.18. Flow rate control protocol: flow rate measurement with computer

The test procedure outlined below can be carried out with a 50 ml or 20 ml syringe. The operating mode described below, reflects the flow rate Measurement software used by Fresenius Vial according to the Pr EN 60-601-2-24 Standard for Infusion pumps. It is up to the user to adapt this procedure to the software he uses.

5.18.1. Equipment used:

- Scales coupled to a microcomputer
  scales sensitivity (in compliance with IEC 601.1 standard, 2nd part):

flow rate value (x)	scale sensivity
x ≤ 5 ml/h	1/10000e
5 ml/h < x 30 ≤ ml/h	1/1000e
x > 30 ml/h	1/100e

- Multi scales acquisition program
- Test tube or beaker with 1 ml graduating
- Liquid: distilled water +/ oil)
- Luer Lock type plastic syringe (50 or 20 ml)
- Catheter extension with Luer Lock end piece (length 100 cm, inside diameter 2.5 mm).
- Needle:

flow rate value (x)	nodale type
x < 30 ml/h	G 26
x ≤ 30 ml/h	G 18 ou G 21

5.18.2. installation

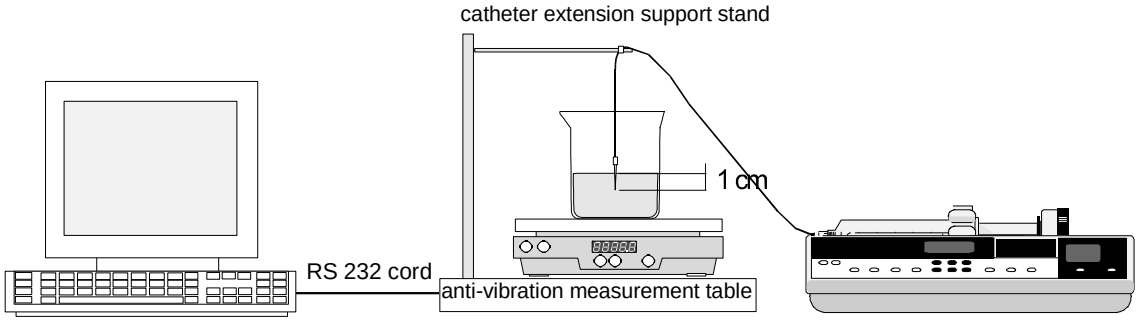
1. The equipment should be installed according to the installation drawings shown in below.
   - **Important**: Make sure that the horizontal installation plane is respected.
2. Fill the syringe with 50 ml of distilled water. Prime if necessary to eliminate any air bubbles.
3. Secure the female Luer Lock end piece of the catheter extension onto the syringe and the male Luer Lock end piece onto the needle.
4. Install the syringe onto the device.
5. Fill the test tube with water ensuring that the needle is dipped in the liquid (1 cm) and add several drops of oil in order to create a greasy film on the surface of the liquid. In this way the user will avoid any measurement error due to evaporation of the liquid.
6. Place the test tube in the centre of the scales platform.
7. Place the needle inside the test tube.
   - **Important**: The infusion line (needle/catheter extension) must not be in contact or rest on the Scales/test tube assembly at any time.
8. Start the device by pressing on the ON key (Injectomat 2000 MC / Pilot Delta in mains supply mode) then prime the infusion line using the PRIME/BOLUS key.
   - **Important**: check that there are no air bubbles.

5.18.3. Operating mode

- Remark: the software works following the operating mode described in the Pr EN 60-601-2-24 Standard for infusion pumps.

1. Start the acquisition program for the scales.
2. Enter the data necessary to carry out the program without validating the flow rate.
3. Adjust the scales to the specified flow rate.
4. Confirm the flow rate on the microcomputer so that the automatic setting of the scales can take place.
5. Start infusion when 00.00 appears on the scales display screen.
6. When the specified time is over, note the error percentage displayed on the screen.

5.18.4. Installation drawing



5.19. Flow rate control: flow rate control measurement with scales

- In compliance with IEC 601.2 standard, 2nd part - 62D standard project for infusion pumps.

5.19.1. Equipment used:

- Stop clock
- Scales - scales sensitivity:

flow rate value (x)	scale sensivity
x ≤ 5 ml/h	1/10000e
5 ml/h < x ≤ 30 ml/h	1/1000e
x > 30 ml/h	1/100e

- Test tube or beaker with 1 ml graduating
- Liquid: distilled water +/ oil)
- Luer Lock type plastic syringe (50 or 20 ml)
- Catheter extension with Luer Lock end piece (length 100 cm, inside diameter 2.5 mm)
- Needle:

flow rate value (x)	needle type
x < 30 ml/h	G 26
x ≤ 30 ml/h	G 18 ou G 21

5.19.2. Installation

1. The equipment should be installed according to the installation drawings shown in 5.18.3.

Remark: Make sure that the horizontal installation plane is respected.

2. Fill the syringe with 50 ml of distilled water. Prime if necessary to eliminate any air bubbles.

3. Secure the female Luer Lock end piece of the catheter extension onto the syringe and the male Luer Lock end piece onto the needle.

4. Install the syringe on the device following the instructions described in the Operator's Guide (See Operator's Guide PILOT anaesthesia 2, Chap. 3: positioning the syringe).

5. Fill the test tube with water ensuring that the needle is dipped in the liquid (1 cm) and add several drops of oil in order to create a greasy film on the surface of the liquid. In this way the user will avoid any measurement error due to evaporation of the liquid.

6. Place the test tube in the centre of the scales platform.

7. Place the needle inside the test tube.

Important: The infusion line (needle/catheter extension) must not be in contact or rest on the Scales/test tube assembly at any time.

8. Start the device by pressing on the ON key (Injectomat 2000 MC / Pilot Delta in mains supply mode) then drain the perfusion line using the PRIME/BOLUS key.

Important: check that there are no air bubbles.

5.19.3. Operating mode

1. Select the flow rate

   - Important: for low flow rates (< 5 ml/hr) validate and wait for the infusion to stabilise for 1 hour. For higher flow rates, 10 to 30 minutes are sufficient for this stabilisation.

2. Set the scales at 00.00 g

3. Start infusion by pressing on the START/CONFIRM key and set off the stop clock at the same time (if necessary make a note of the stop clock start value).

4. The test lasts for 1 hour. When over, press on the STOP key to stop the infusion.

5. Note the value in grams of "infused" liquid.

6. Calculate the difference between the design value and the real value.

Remark: 1 gram = 1 ml.

7. The error percentage can be calculated from this difference.
   Formula:

$$\frac{\text{Measured value - Design value}}{\text{D designed value}} \text{ X 100 = percentage}$$

5.20. Flow rate control: flow rate measurement using a test tube

5.20.1. Equipment used

- ❑ Stop clock
- ❑ Test tube or beaker with 1 ml 0.5 ml graduating
- ❑ Liquid: distilled water +/ oil)
- ❑ Luer Lock type plastic syringe (50 or 20 ml)
- ❑ Catheter extension with Luer Lock end piece (length 150 cm, inside diameter 2.5 mm).
- ❑ Needle

flow rate value (x)	needle type
x < 30 ml/h	G 26
x ≤ 30 ml/h	G 18 ou G 21

5.20.2. Installation

1. The equipment should be installed according to the installation drawings shown in 5.18.3.
   - ❑ Remark: Make sure that the horizontal installation plane is respected.
2. Fill the syringe with 50 ml of distilled water. Prime if necessary to eliminate any air bubbles.
3. Secure the female Luer Lock end piece of the catheter extension onto the syringe and the male Luer Lock end piece onto the needle.
4. Install the syringe on the device.
5. Fill the test tube with water ensuring that the needle is dipped in the liquid (1 cm) and add several drops of oil in order to create a greasy film on the surface of the liquid. In this way the user will avoid any measurement error due to evaporation of the liquid.
6. Place the needle inside the test tube.

5.20.3. Operating mode

1. Select the flow rate
   - ❑ Important: for low flow rates (5 ml/h) validate and wait for the infusion to stabilise for 1 hour. If possible, use a smaller test tube guaranteeing greater precision in ml reading. For higher flow rates, 10 to 30 minutes are sufficient for this stabilisation.
2. Start infusion by pressing on the START/CONFIRM key and set off the stop clock at the same time (if necessary make a note of the stop clock start value).The length of the test is determined by the time necessary for a 50 ml infusion in the test tube.
3. Calculate the difference between the design value and the real value.

$$\text{Real flow rate} = \frac{50 \text{ ml}}{\text{Time in hours}}$$

4. The error percentage is calculated from this difference (Measurement error +/-1%*),*

$$\frac{\text{Measured value - Design value}}{\text{D designed value}} \times 100 = \text{percentage}$$

6 ANNEX 1: ILLUSTRATED PARTS LIST

6.1. Subassembly traceability table

6.1.1. Introduction

This chapter allows the technician to find which component has been changed on the product, also to order the right part when it necessary for the pump maintenance.

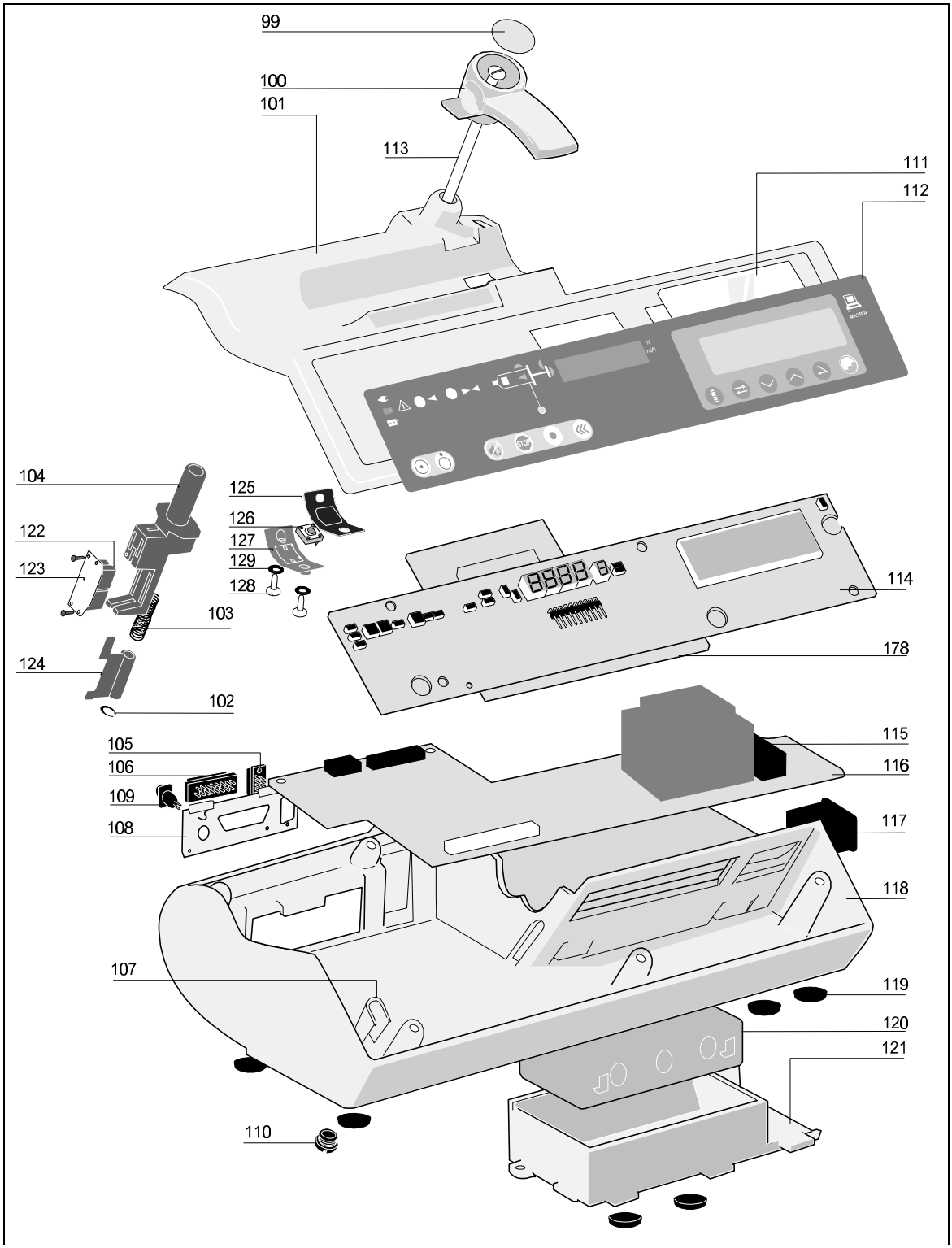
6.1.2. Replacement parts table

The table below list the main modification made to improve the product. The Injectomat 2000 MC / Pilot Delta serial number should be used when looking for components.

Equivalence table for Injectomat 2000 MC / Pilot Delta			
Serial N°	From: 16685686 To : 18091461	From: 18091461	
Display board	167549	167566	
CPU board	167568	167543	
Power supply and control board	167557	167537 (Injectomat) 167536 (Pilot Delta)	
Eprom	167991-V1.1a	167991-V1.2a	
Upper case IEC kit	199250	199250	
Upper case export kit	199251	199251	
Lower case IEC kit	199200	199200	
Lower case DIN kit	199201	199201	
Lower case NL kit	199202	199202	
Lower case IS kit	199203	199203	
Wired motor	167965	167965	
Battery connector	167961	166901	
Potentiometer wired	167963	167963	

6.2. Exploded views and related parts lists

6.2.1. Mechanical part list



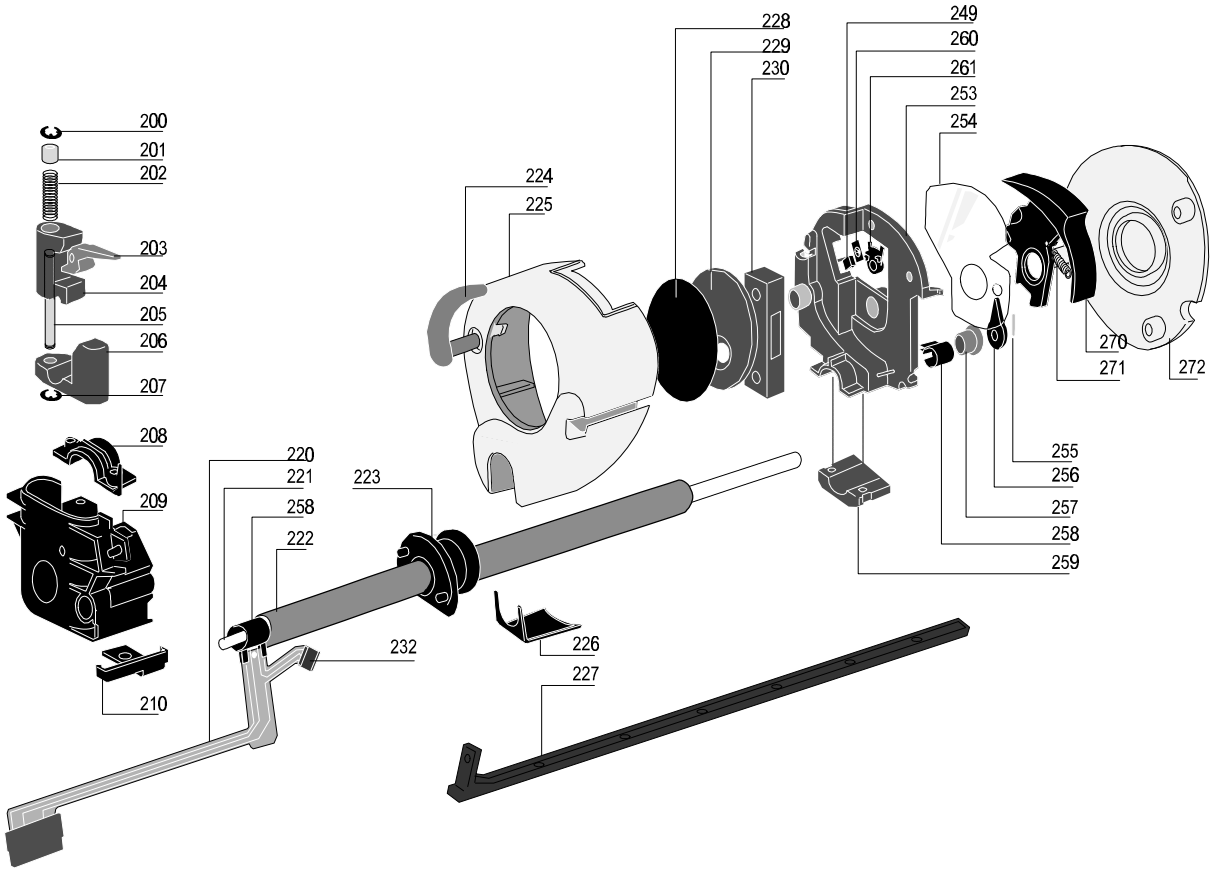
Upper and lower cases

6.2.1.1. Upper case

Reference	Repère	Quantity	Designation
167744	99	1	Diam.17.5 Pilot Delta
167681	99	1	Diam.17.5 Injectomat
167476	100	1	Syringe clamp Pilot Delta
167516	100	1	Syringe clamp Injectomat
167458	113	1	Syringe clamp shaft
167361	102	1	Diam 5 retaining ring
167310	103	1	Syringe clamp compression spring
167452	104	1	Injected PC opto support
168343	111	1	PILOTE ANES window
167679	112	1	Injectomat 2000 MC German front panel
168159	112	1	Pilot Delta French front panel
167627		1	Injected Diam.6 block
199560		1	Female hybrid M3x12 spacer
167067		1	CPU board protector film
167632		1	Buzzer foam
167042	122	2	Opto
167178	123	1	Flange pilot opto IC
167462	124	1	Pilot 20/60 cc shutter
167377	125	1	Flange pilot switch joint
167365	126	1	ALPS SKHCAF switch
167376	127	1	Flange pilot switch support
199618	128	1	TCB 2.2 x 8 Eco-Syn screw
199518	129	1	Flexible stiffened washer
167632		1	Buzzer bell foam

6.2.1.2. Lower case

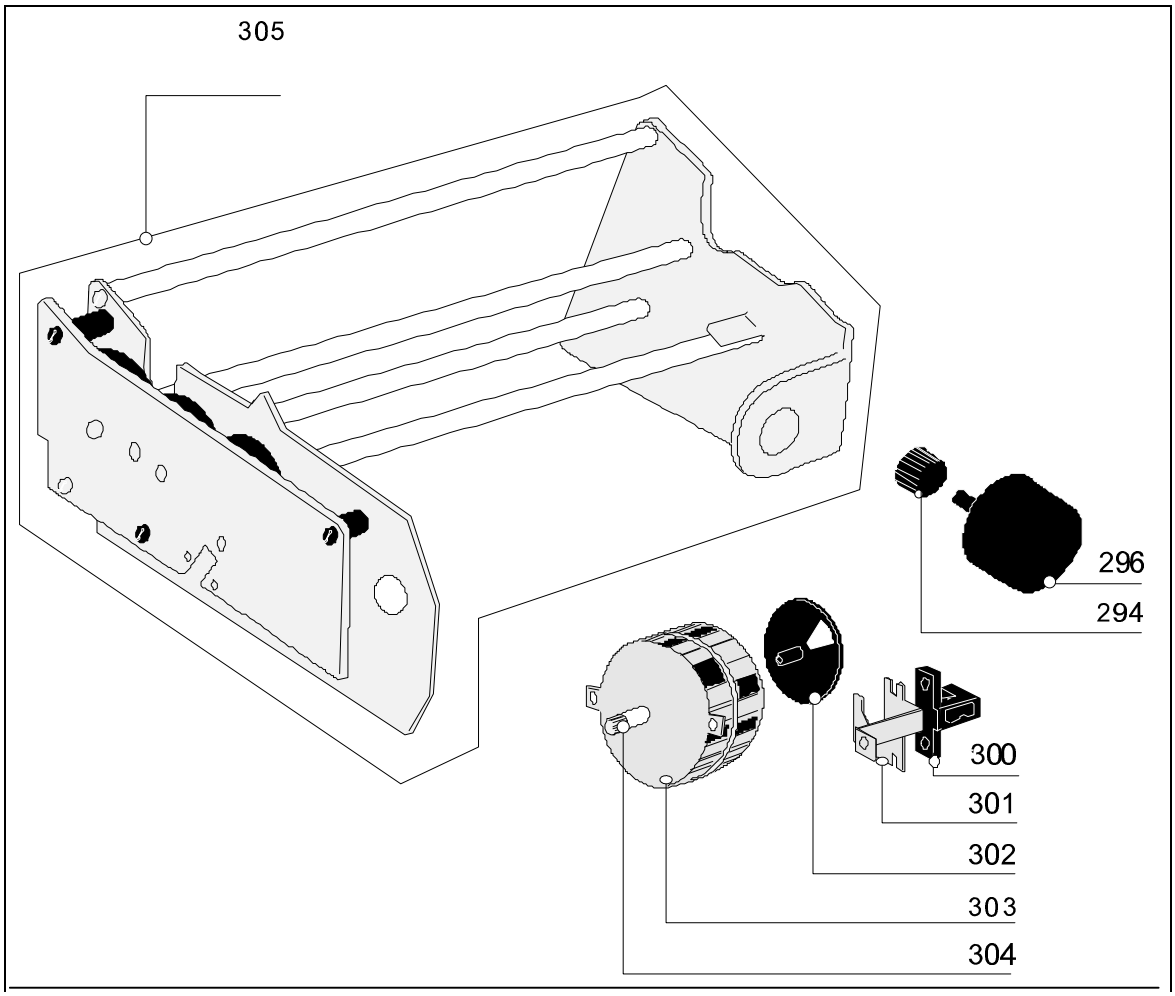
Reference	Repère	Quantity	Designation
170685	105	1	9 points Sub d
170687	106	1	15 points Sub d
177201	115	1	16 VA transformer
167942	117	1	Main socket support
167093	107	1	Buzzer bell
167285	108	1	Socket support
167200	109	1	3 points female socket
167432	110	1	Injected buzzer adjustment button
167059		1	Guide rail (Pilot Delta)
167514		1	Guide rail (Injectomat)
167299		1	Buzzer adjustment washer
167297		1	Buzzer flexible washer
167249	119	6	Adhesive black block
174019	120	1	6V 1.2/1.3 Ah battery
166901	121	1	Wired Battery sockets HE 13
167122		1	flexible Circuit retainer, Injected
167355		1	Main socket fiber joint



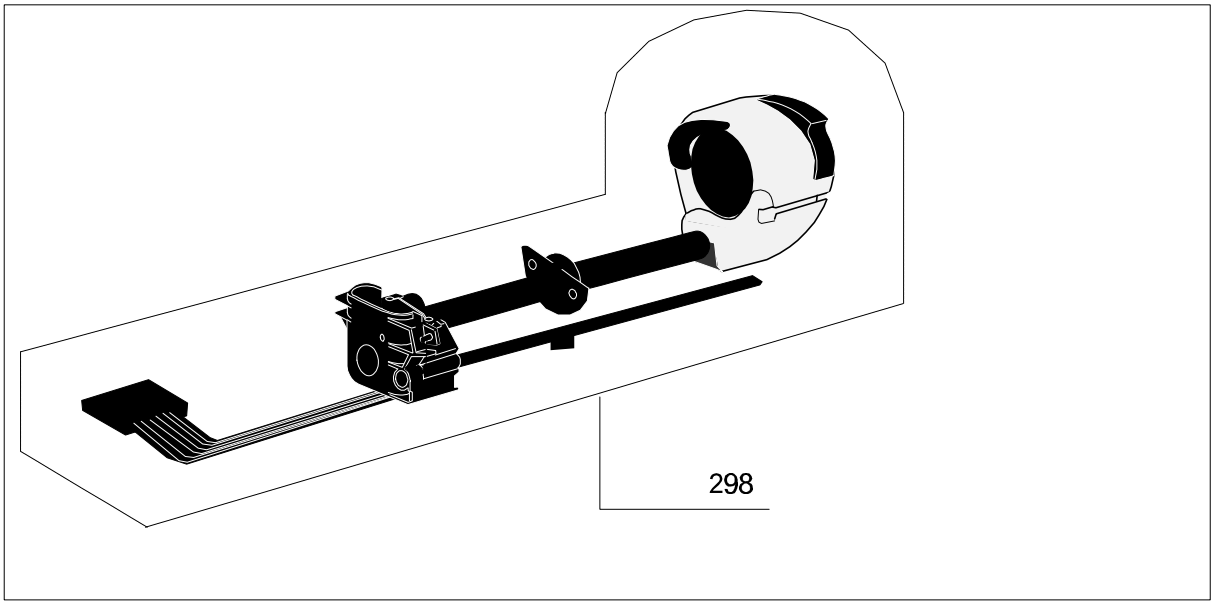
Mechanical plunger unit PILOT anaesthesia 2

6.2.1.3. Plunger / mechanism unit

Ref.:	Diag. Ref.	Number	Component
167360	200/207	2	Diam. 3.5 mm retaining ring
167465	201	1	Half nut spring cap
167469	202	1	Half nut spring
167460	203	1	Disengagement came
167471	204	1	Upper machined half nut
167472	206	1	Lower machined half nut
167475	208	1	Tube retainer
167281	209	1	Mechanical block + injected pad
167275	210	1	Flexible circuit clip
167271	220	1	Flexible circuit
167241	221	1	Complete disengagement shaft
167292	222	1	Diam.12 tube(version 20/60 ml)
167403	223	1	Injected centring ring
177203		1	O ring (to be placed in the centring ring)
177204		1	Inox plate (To be placed between the centring ring and the flask)
167291	224	1	Anti-siphon arm
167521	225	1	Pusher housing (injectomat)
167382	225		Pusher housing (Pilot Delta)
167259	226	1	Pusher housing clip
167442	227	1	Injected M 0.5 rack
167683	228	1	Diam. 36 protective sticker
167384	229	1	Injected contact plate
167132	230	1	Force sensor
173408	232	1	OMRON microswitch
162311	249	1	RP I 131 type photo inter
167288	253	1	C pusher support
167497	254	1	Pusher protection film
168231	256	1	Disengagement finger
167298	258	2	Flexible circuit protector
167272	259	1	Pusher/tube fastener
190714	260	1	Retaining ring
167385	261	1	Anti-siphon came
167264		1	Anti-siphon spring
167260	270	1	Disengagement lever
167245	271	1	Disengagement lever spring
167056	272	1	Pusher cover (Pilot Delta)
167519	272	1	Pusher cover (Injectomat)
167464	205	1	Half nut spring shaft
167487	257	1	Disengagement shaft bearing



Motor reduction bloc



Mechanical kits

6.2.1.4. Motor reduction block

Reference	Diag. Ref.	Number	Component
176443	294	1	Injected M5 gear
167963	296	1	HE13 wired potentiometer
167128	300	1	Motor rotation photo switch
168401	301	1	Support opto
167111	302	1	Motor rotation blade
167082	303	1	Pilot 2 Ph motor
167153	304	1	Pilot motor gear
167101	305	1	R100 reduction gear mainframe

6.2.1.5. Mechanical kits

Reference	Diag. Ref.	Number	Component
170416		1	Main cord
167969	105/6/8/9	1	HE13 wired socket support C/D (Pilot Delta)
199188	105/6/8/9	1	HE13 wired socket support C/D (Injectomat)
167659	122/123	1	HE13 wired opto printed circuit
199136	298	1	pilot anest 2 mechanical kit

6.2.2. Electronical parts list

6.2.2.1. VA Power supply board

Reference	Diag. Ref.	Number	Component
167536	116	1	Injectomat 2000 MC / Pilot Delta RS232 HE13 power supply board (Pilot Delta)
167537	116	1	Injectomat 2000 MC / Pilot Delta RS232 HE13 power supply board (Injectomat)

6.2.2.2. led display board

Reference	Diag. Ref.	Number	Component
167566	114	1	PILOT Anaesthesia 2/B 9 LEDS display board

6.2.2.3. CPU board

Reference	Diag. Ref.	Number	Component
167543	178	1	CPU board W. flange det. ANT + HE13

Warning

A Injectomat 2000 MC / Pilot Delta CPU Board should never be used on Pilot C, and vice versa. A CPU board is configured for one device type only. This configuration include the calibration modes depends to the components characteristics, the syringe list specific to the product code and the pump serial number located on the pump identifical label stacked on the lower housing.

6.2.3. Operator's guide of Injectomat 2000 MC / Pilot Delta(NU)

It is possible to get this Operator's guide, references:169540 (Injectomat 2000 MC in German), 169545 (Injectomat 2000 MC in English), 169610 (Pilot Delta in French) on simple request to our commercial service (see useful addresses chapter 9).

6.2.4. Labels

6.2.4.1. Door Label

FR	DIN	IS	BNF	IT	SP	S	B	P
167892	167892	167892	167892	167892	167892	167892	167892	167892

6.2.4.2. Danger selection label

FR	DIN	IS	BNF	IT	SP	S	B	P
167741	167979	167776	167811	167778	167858	167886	167692	167692

6.2.4.3. Battery door label

FR	DIN	IS	BNF	IT	SP	S	B	P
167196	167196	167196	167196	167196	167196	167196	167196	167196

6.2.4.4. Main DANGER label (inside)

FR	DIN	IS	BNF	IT	SP	S	B	P
171091	171091	171091	171091	171091	171091	171091	171091	171091

6.2.4.5. Mains label(outside)

FR	DIN	IS	NL	IT	SP	S	B	P
168197	168197	168197	168197	168197	168197	168197	168197	168197

7 ANNEX 2: ELECTRONIC LAYOUT

7.1. Power supply and control board

7.1.1. Electronic layout

Designation	DESIGN. REF
Motor power supply and control board (5/5 X A3)	D1A0DB000

7.1.2. Installation layout

Designation	DESIGN. REF
Motor power supply and control board *Pilote* Delta (1/1 x A3)	D3A0DB004
Motor power supply and control board Injectomat 2000MC (1/1 x A3)	D3A0DB005

7.2. CPU board

7.2.1. Electronic layout

Designation	DESIGN. REF
CPU board (3/3 x A3)	D1A0EY00

7.2.2. Installation layout

Designation	DESIGN. REF
CPU board *PILOTE AILETTE RS232 (C)* (1/2 x A3 only)	D3A0EY00

7.3. Display board

7.3.1. Electronic layout

Designation	DESIGN. REF
Display board Pilote anesthesie 2 (3/3 x A3)	D197GT000

7.3.2. Installation layout

Designation	DESIGN. REF
Display board Pilote anesthesie 2 (2/2x A3)	D397GT000

8 ADDENDA AND INFORMATION BULLETINS

9 USEFUL ADDRESSES

All requests for information or documentation (technical file, tubing catalogue or commercial documentation should be addressed to:

CUSTOMER SERVICE INTERNATIONAL

	Fresenius Vial Le Grand Chemin, 38590 Brezins FRANCE	Tel.: 33 (0)4 76 67 10 81or 10 54 Fax: 33 (0)4 76 65 52 22

AFTER-SALES SERVICES

INTERNATIONAL	**Fresenius Vial** Le Grand Chemin, 38590 Brezins FRANCE	Tel.: 33 (0)4 76 67 10 76 Fax: 33 (0)4 76 65 56 66
BELGIUM	**FRESENIUS NV/SA Belgique** **DIVISION VIAL MEDICAL** Molenberglei 7 2627 Schelle BELGIQUE	Tel.: 32/3 880 73 07 Fax: 32/3 880 50 07
GERMANY	**FRESENIUS MCM** AM-NEUNEN BERG 8 63749 ALZENAU GERMANY	Tel.: 49/60 23 97 22-0 Fax: 49/60 23 43 06

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